

2019

# WHEN SCIENCE AND BIODIVERSITY MEET ECONOMIC INTERESTS

The last 10 years of "evolution" in pesticides risk  
assessment on bees



**'SINCE SOME SPECIES OF BEES LIVE IN SOCIETIES, THE SUBLETHAL EFFECTS ON INDIVIDUAL BEES AND THE COLONY ALSO NEED TO BE STUDIED.'**

The evaluation of the impact of pesticides on human and animal health and the environment is a legal obligation in Europe. The obligation also includes the evaluation of their effects on bees, as they are part of the environmental dimension. Regulation (EC) No 1107/2009 defines the criteria that need to be fulfilled for the European marketing of an active pesticide substance. For bees, it states:

*“An active substance, safener or synergist shall be approved, only if it is established following an appropriate risk assessment, based on Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:*

- *will result in a negligible exposure of honeybees,*

*or*

- *has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour”.*

*Regulation (EC) N° 1107/2009, Annex II, 3.8.3 [1]*

When a company that produces plant protection products applies to release an active chemical substance or a pesticide formulation into the European market, it must provide the competent authorities with a registration dossier, containing the required data and information defined by law (Regulations (EC) No 283/2013[2] and 284/2013 [3]). It includes data on the toxicological effects and the possible ways of exposure of bees to pesticides.

In the case of bees, they need to provide information about the toxic effects provoked by a single contact with the substance (acute toxicity) and those induced by continuous or repeated contact with the pesticide (chronic toxicity). Some pesticides have proved to affect only bees in development and not adults, reason why the impacts on larvae are also studied during the pre-authorisation of the active chemical substance. Since some species of bees live in societies, like honeybees or bumblebees, the sublethal effects on individual bees (effects that do not cause immediate death, but which damage the normal development/behaviour of bees), and on the colony also need to be studied. For example, by evaluating the effects on the social behaviour of bees and their reproductive success.

Science and field observations by beekeepers have shown that pollinators can get in contact with pesticides through various ways, i.e. their food sources like nectar, pollen and water, including water exuded by plants; while flying through dust particles and spray-drift or volatile chemicals diluted in the air, soil, leaves, and others. Therefore, it is also imperative to obtain data on the toxic residues which pesticides produce in the broader environment before the introduction in the market.

Public agencies or governments, together with the European Food Safety Authority (EFSA), are responsible in Europe for evaluating the impact that chemicals, including pesticides, will have once they are authorised. They are also responsible for monitoring the level of contamination of our food and water. These agencies often seek to have standard methodologies to execute such evaluations, and their approach towards risk assessment of pesticides on bees has been somehow similar ever since member states decided to join forces and move from a national to a European authorisation of pesticides. The challenging question is then “how do we define workable, effective guidelines for assessing the risks that pesticides pose to honeybees, bumblebees, solitary bees and other pollinators?”

Science and field observations by beekeepers have shown that pollinators can get in contact with pesticides in various ways, including nectar, pollen, dust particles and water.

## **EFSA GUIDANCE: CURRENT SCIENTIFIC METHODOLOGY DEEMED THE MOST APPROPRIATE FOR ASSESSING PESTICIDE-RISKS FOR BEES**

Already in 2010, BeeLife, formerly European Beekeeping Coordination, highlighted the deficiencies of the current Pesticide Risk Assessment for bees in the EU. In the same year, in collaboration with Corporate Europe Observatory (CEO), BeeLife also revealed that the European Commission, was ‘unknowingly’ devolving the expertise on risk assessment methodology to pesticide manufacturers [4], which constituted a major conflict of interest.

In recognition of this conflict of interest, the Commission (DG SANTE) responded quickly by requesting its food safety experts, EFSA, to re-evaluate the scientific basis of pesticide risk assessment for bees.

As a result, in 2012, EFSA published a scientific opinion [5] produced by several bee ecotoxicologists. It revealed significant weaknesses and gaps in the Risk Assessment Methodology of the time. Problems included: failure to deal with chronic toxicity or sublethal effects, failure to deal with larval toxicity, and the dismissal of various routes of toxic exposure through water, food (pollen, nectar) or air (seed dust).

The resulting EFSA scientific opinion was the basis of a guidance document proposed by bee ecotoxicologists and risk assessors, which proposed a new Risk Assessment Methodology. It was finally published in 2013 and popularised as the « EFSA Guidance on bees [6] ». Various public consultations were held by the Agency to strengthen this document, ensuring that the process was not only scientifically sound but also transparent and democratic. To date, these guidelines recommend the only methodology which would allow us to analyse and interpret the toxicology and exposure data required by EU law, for the risks which pesticides pose to bees and pollinators.

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## **WHEN SCIENCE MET ECONOMICS**

The publication of the EFSA Guidance provoked a strong reaction of the agro-chemical companies who qualified the methodology as over-conservative, excessively complicated and inapplicable. In practice, the EFSA Guidance document allowed much less room of manoeuvre for the industry to run tests and could potentially demand them to run more field trials than those they currently do. It involves a substantial investment from their side.

The outcome of the application of the EFSA risk assessment methodology leads to a better description of the risk that pesticides pose to bees, which in turn may lead risk managers to restrict the authorisations of pesticides. Many risk assessors of the EU countries seconded the arguments put forward by industry, and the member states have blocked the implementation of the EFSA Guidance document ever since.

We review some of the arguments against the adoption of the EFSA Guidance document:

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## Arguments against the adoption of the EFSA Guidance document

### **1. It will be impossible to register any insecticides and very difficult to register many fungicides and herbicides under the new guidelines.**

This argument is UNTRUE because risk assessment is NOT risk management.

Risk assessment is carried out before the authorisation of any pesticide, medication or agent that could damage human or animal health or the environment. It is a phase in which necessary data to learn about the pesticide is produced, including its behaviour once in the environment, its benefits (efficacy, etc.) or risks (carcinogenicity, mutagenicity, toxicity to non-target animals or plants, etc.).

It is therefore essential to have suitable methods that allow an understanding of the characteristics of the pesticides as best as possible.

Based on the information produced in risk assessment, risk managers make their decisions on the authorisation of the pesticides: for which crops, when/how/how much to use them, etc.

Consequently, the better the pesticides are known, the best use farmers will be able to make from these tools.





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## **2. The guidance document has unrealistic trigger values which fail to distinguish the substances requiring additional testing in the field.**

This second argument is also UNTRUE because EFSA already did a sensitivity analysis on pesticides, not just insecticides, that would require further testing. New evaluation methods are based on a battery of inexpensive laboratory tests providing a screening of possible toxic effects on bees. This means that already in the lab, we will be able to know if a pesticide can be risky/harmful for bees in the short or the long term, for adult bees or immature bee stages.

Risk coefficients are then used to determine if further testing is required to better understand the impact of pesticides once in the environment. These risk coefficients relate toxicity and exposure: the same risk may come from a very toxic pesticide that is used in minimal quantities than from a low toxic pesticide that is used everywhere in high quantities.

These risk coefficients are the result of careful calculations from EFSA, based on scientific data. Before proposing these risk coefficients, EFSA made sensitivity analyses to evaluate the proportion of active substances that would require further testing.

The fact that further tests, such as tunnel or field trials, are required does not mean that the pesticide “failed” the risk assessment and that it will not be authorised. It merely means that risk is possible, and there is a need to understand better how bees can get in contact with the pesticide in real conditions. Furthermore, industries have no data to claim such a thing.

## **3. The guidance document is complicated, conservative and impractical.**

This is UNTRUE, and complication should not be confused with completeness. The guidance document proposed by EFSA follows the same logic for performing a risk assessment as to what existed before. However, this guidance document allows to know the toxicological profile of pesticides before their marketing better, e.g. if it is toxic to larvae or adults; if it is more toxic to wild bees than managed ones, etc. Therefore, it is much more complete to perform a pesticide risk assessment on bees than any other guideline ever developed. It also takes into consideration: water, air, etc.

European Food Safety Authority, 2013  
*Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees).*

Furthermore, EFSA has already developed tools for running risk assessment procedures to ease the work of risk assessors. It is the first time that risk assessors count with these tools to develop their work.

#### **4. The guidance document removes many possibilities of conducting realistic field testing - by setting the criteria so high, it becomes impossible to produce a compliant study.**

This is UNTRUE. Considering the intensive agricultural model we have in Europe, the most common situation is that bees, with a radius of foraging of at least 3 km, are exposed to more extensive treated areas than those used in the field trials. If we consider that a pesticide can be authorised for different crops, what could also happen in real conditions is that bees are exposed to a pesticide over more extended periods than those proposed in field trials.

The solution to overcome this reality, however, is not to deny the work developed by EFSA regarding the improvement of the performance of field trials. The way to overcome this limitation from real conditions is by also monitoring them: once on the market, bees or pollen could be monitored to evaluate the level of exposure to authorised pesticides.

BeeLife has compiled other arguments put forward by the pesticide industry and some EU countries [7].

Risk assessors of the EU countries can only use the proposed EFSA Guidelines after the Standing Committee on the Food Chain, and Animal Health (SCOFCAH) approves them. This committee is composed of EU Commission (DG SANTE) and representatives of national member states (generally the ministry of agriculture or health). Ever since the EFSA Guidelines were published in 2013, the Commission has pushed for their approval, but member states have failed to achieve a qualified majority for adoption of the new methodologies. Through this strategy, some member states have deliberately blocked the implementation of the new Guidelines, to avoid the adoption of an improved and appropriate risk assessment of pesticides for bees in Europe. The legal and scientific bases are all in place, but this political blockage prevents the adoption of the new Guidelines due to the economic interests of member states or lobbying by pesticide producing companies.

The main arguments of member states are that the EFSA Guidelines are too complicated to be implemented, and some parameters are inadequate. However, due to a lack of transparency, it is challenging to obtain detailed information on the actual position of Member States. Pesticide companies, from their side, fear that the EFSA Guidelines are going to hamper the marketing of their products and hence their profits.

### **WHAT HAS HAPPENED FROM 2013?**

The Commission proposed to the member states the adoption of the EFSA methodology for risk assessment of pesticides on bees. This is done at a Standing Committee, managed by the Commission and composed of representatives of national Member States (generally the ministry of agriculture or health) who vote on the implementation of laws linked to food safety and animal health and welfare. Risk assessors of the EU countries are entitled to use the EFSA Guidance document after the EU countries have accepted it. On the other hand, no member state can be stopped to use the guidelines if they wish to. Since their publication in 2013, the Commission has pushed for the approval of the guidelines, but member states have not achieved a qualified majority for their adoption.

**'THE GUIDANCE DOCUMENT PROPOSED BY EFSA FOLLOWS THE SAME LOGIC FOR PERFORMING A RISK ASSESSMENT AS TO WHAT EXISTED BEFORE BUT ALLOWING TO KNOW THE TOXICOLOGICAL PROFILE OF PESTICIDES BEFORE THEIR MARKETING BETTER.'**



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The presented arguments by member states, however, resemble those of the pesticide industry.

In 2015, the EFSA pursues its work on bees in parallel to the political discussions between the Commission and the member states by launching the project MUST-B. The objective of this project is to develop a holistic approach to the risk assessment of multiple stressors in honeybees. This project involves a paradigm shift in pesticide risk assessment, as it no longer alienates pesticide exposure of bees from other stressing factors like pathogens, parasites, or weather [8].

In May 2016, the Commission presented a draft implementation plan for the risk assessment scheme laid down in EFSA Guidance Document. National representatives were requested to express their positions on the draft [9] and in December 2016, the Commission presented a revised plan to the EU countries [10]. In 2018, face to the immobilism of EU countries in the implementation of the accepted plan, the Commission presented a second revised draft in July 2018 [11]. In the same month, the Environment Committee of the European Parliament requested the EFSA to develop an opinion on the science behind the development of a holistic approach for the risk assessment of multiple stressors in managed honey bees (*Apis mellifera*). This involves that in the future, the “Bee Guidance Document” most likely will integrate the multi-stressors approach proposed by the MUST-B project. Therefore, in parallel with the political immobilism of decision-makers, researchers from the EFSA continue their work, the objective being to integrate the effects of possible multi-stressors in risk assessment.

In June 2018, the European Commission adopted the EU Pollinators Initiative. This initiative was a major development in advancing the protection of pollinators, with unprecedented objectives and deployment. It was adopted after a public consultation with over 65.000 responses. The Initiative text even states that “The Commission will adopt an implementation plan for the EFSA Guidance Document” [12].

At the Standing Committee meeting of October 2018, the Commission asked each country to state its position. It recorded that “16 Member States indicated the need to revise the Bee Guidance Document first before it being implemented; 9 Member States could support the current implementation plan; 2 Member States did not have a position” and “1 Member State was absent and not represented” [13].

Health and Food Directorate General,  
2018, *SUMMARY REPORT OF THE  
STANDING COMMITTEE ON PLANTS,  
ANIMALS, FOOD AND FEED HELD IN  
BRUSSELS ON 19 JULY 2018 -20 JULY  
2018*

**'MANY ENVIRONMENTAL AND CONSUMER NGOS HAVE COME TO SUPPORT THE INITIAL WORK DEVELOPED BY BEE LIFE, CONVINCED THAT THERE IS STRENGTH IN NUMBERS, AND BEES AND BIODIVERSITY PROTECTION NEED ALL THE SUPPORT THEY CAN GET.'**



Meanwhile, EFSA used the Guidance document for the re-evaluation of the risk of three neonicotinoid insecticides and fipronil following the request of the Commission. The outcome of the risk assessment allowed for a better description of the risks for bees once neonicotinoids are applied in the field. Risk managers had a better picture of the risks involved and decided to limit the authorisation of these products to greenhouses.

On the side of civil society, many environmental and consumer NGOs have come to support the initial work developed by BeeLife, convinced that there is strength in numbers, and bees and biodiversity protection need all the support they can get. The Bee Coalition was created in 2017 to join forces and resources at EU level for the protection of bees and pollinators. Unfortunately, the subject is so technical that even civil society gets lost in the discussions. Nevertheless, it is crucial to maintain the pressure on national governments to make sure that pesticides do not get into the fields without a proper risk assessment. It is vital that we, EU citizens, ask our governments to make the best-informed decisions, based on scientifically based protocols.

### 2019, YEAR OF HOPE?

In January 2019, the Commission asked each member state again to position itself. The result was that 18 member states indicated to support the revision of the second implementation plan, 3 member states indicated not to support the implementation plan; 7 member states did not have a position yet or were absent [14], according to the Commission's summary of the meeting.

Face to the blockage that member states put on the implementation of the EFSA Guidance document and their permanent request of a review of the methodology, the Commission asked EFSA to review its Guidance document. The EFSA is currently seeking experts from the stakeholders to integrate as many views as possible on the development. In parallel, EFSA is developing a scientific review to answer to the mandate of the European Parliament. We hope that the EFSA will optimize resources and will integrate the knowledge for both achieving an update of the Bee Guidance Document and including a holistic approach for the risk assessment of multiple stressors. We only hope that country experts will be seated next to stakeholders so we can get the best possible evaluation of the impact of future pesticides in Europe. While scientific knowledge continues to advance, improving measures for risk assessment of phytosanitary products, legislation has slowly been falling behind. In need of scientific-based advances for risk assessment and policies, governments and institutions will need to rely on its scientific and safety authority.

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