Struggle for the Implementation of New Pesticide Assessment Methods with Regards to Bees
The Truth behind the Excuses

The EFSA, European Food Safety Authority, published in 2013 a new methodology for carrying out the risk assessment of pesticides on bees, prior to their market introduction. Three years later it has not been yet implemented because the pesticide industry and some Member States block its application. However, this is the only methodology permitting to accurately assess the risks of pesticides for pollinators, as intended by European law.

Pesticide industry and some Member States have delayed for 3 years these new methods to perform the evaluation of the risks of pesticides to bees. Actually, industry claims that Member States refuse to adopt these methods and put in the mouth of Member States all the arguments affecting itself. These arguments, together with an evaluation of their truthfulness, are set out below.

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

WRONG!

Risk assessment is NOT risk management.

Risk assessment is carried out before the authorisation of any pesticide, medicament or agent that could damage human or animal health or the environment. It is a phase in which a number of data is produced in order to know the pesticide: 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 important to have good methods that allow to know 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.

WRONG!

The guidance document is complicated, conservative and impractical.

Complication should not be confused with completeness.

The guidance document proposed by the EFSA follows the same logic for performing risk assessment as to what existed before. However, this guidance document allows to better know the toxicological profile of pesticides before their marketing, e.g. if it is toxic to larvae or to adults, if it is more toxic to wild bees than managed ones, etc. Therefore, it is much more complete to perform pesticide risk assessment on bees than any other guideline ever developed. It also takes into consideration: water, air, etc.

Furthermore, the 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.

WRONG!

The guidance document has unrealistic threshold values which fail to distinguish the substances requiring additional testing in the field.

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 in the long term, for adult bees or the 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 very little quantities, than from a low toxic pesticide that is used everywhere in high quantities.

These risk coefficients are the result of careful calculation from the EFSA based on scientific data. Before proposing these risk coefficients, the EFSA made a sensitivity analyses in order to evaluate the proportion of active substances that would require further testing. The proportion of substances that would NOT require further testing than laboratory tests is shown in the following table:

	Insecticides	Fungicides	Herbicides
Acute contact	41,6%	100,0%	100,0%
Acute oral	41,6%	100,0%	100,0%
Chronic oral	25,0%	70,0%	27,3%

Source: EFSA

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 simply means that a risk is possible and there is a need to better understand how bees can get in contact with the pesticide in real conditions.

Furthermore, industries have no data to claim such a thing.

The guidance document was produced under emotional stress, following bee losses in Europe, whereas the situation is better than what was expected.

WRONG!

Bee losses in Europe started in the previous century, far before 2012.

Beekeepers have been complaining about bee losses linked to pesticides since the '80s. Scientific studies have also shown detrimental trends in wild bees (Biesmijer et al. 2006 [1]). Stating that the guidance document was produced under emotional stress, is closing the eyes on the real situation of pollinators.

The guidance document is based on a number of worst case hypotheses instead of on realistic scenarios.

WRONG!

This statement is fallacious

Risk assessment was, is and will always be based on worst case assumptions. It is by definition theoretical, because it aims to estimate if problems will be observed once the product is on the market.

Unfortunately, reality has shown far too many times that, despite these worst case assumptions, reality goes beyond fiction. Large bee losses have happened due to a wrong/inadequate evaluation of the risk of pesticides. To name a few: insect growth regulators, like fenoxycarb, microencapsulated insecticides, formulations with dimethoate, or toxic dust clouds released from the sowing of neonicotinoid-treated seeds.

The guidance document goes beyond what the regulation demands

WRONG!

The guidance document of the EFSA is the only methodology available meeting the approval criteria established by the Regulation (EU) 1107/2009 on the marketing of pesticides. Annexe II, Point 3.8.3., of the regulation states:

"*An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of 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.**"*

The guidance document would result in damage to farming in Europe because farmers would not be able to protect crops any longer.

WRONG!

Speculative

As previously stated, the guidance document allows to better know the risks of pesticides to pollinators in order to better protect for farmers the vital service for agronomic production that is pollination. Better knowing the risks may help using pesticides wisely and choose those pesticides or practices involving pesticides that have less impact on our environment.

Furthermore, it is speculative to predict that farmers would not be able to farm correctly anymore. Next to pesticides, farmers have numerous tools to develop their work: agronomic (rotation, etc.) mechanic (weed removal, etc.), biological (nematodes, bacteria, etc.) and genetic (resistant varieties) practices.

Methodologies for some tests are not available.

TRUE

The methodologies for testing toxicity of pesticides to wild bees need further development. However, this is only a portion of the methodology proposed by EFSA. Apart from these, the remaining tests exist already.

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.

WRONG!

Considering the intensive agricultural model we have in Europe, the most frequent situation will be that bees, with a radius of foraging of at least 3 km, are exposed to treated areas much larger 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 longer periods of time than those proposed in field trials.

The solution to overcome this reality, however, is not to deny the work developed by the EFSA in improving the way field trials should be performed. The way to overcome this limitation coming from real life is by monitoring real life: once on the market, bees or pollen could be monitored in order to evaluate the level of exposure to authorised pesticides.

[1] Biesmeijer, J.C., Roberts, S.P.M., Reemer, M., Ohlemüller, R., Edwards, M., Peeters, T., Schaffers, A.P., Potts, S.G., Kleukers, R., and Thomas, C.D. (2006). Parallel declines in pollinators and insect-pollinated plants in Britain and the Netherlands. Science *313*, 351–354.

Specifically, ECPA proposed in a recent position paper (of 28 April 2016) a number of criteria that should be imposed before any new Bee guidance document is to be proposed. We have also some reflections on these criteria.

European Crop Protection

"The protection goals should be set at realistic level, whereas trigger values and criteria for higher tier data should be defined according to these realistic protection goal."

Current protection goals involve that the use of a pesticide cannot have an effect on the pollination service of bees, nor can it have an effect on bee products. These protection goals are realistic and in coherence with the legal framework defined by Regulation (EC) 1107/2009, Article 4, Point (e):
"(e) it shall have no unacceptable effects on the environment, having particular regard to the following considerations where the scientific methods accepted by the Authority to assess such effects are available:

(i) its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range environmental transportation;

(ii) its impact on non-target species, including on the ongoing behaviour of those species;

(iii) its impact on biodiversity and the ecosystem. "

European Crop Protection

"The need for additional testing should be defined based on risk assessment needs and not on a systematic basis."

This was and continues being the case. Higher tier tests are only requested if the toxicity values obtained in lab and the residues found after normal uses show there might be a risk.

So far, risk assessment was done on the basis of acute (short term) toxicity on adult bees, which has been proved to be highly insufficient. However, field data have shown that the exposure of bees to pesticides also happens in the long-run. Field and scientific data have also shown that toxicity in adults differs from that in immature stages. For these reasons, the EFSA guidance includes a battery of inexpensive laboratory tests evaluating acute and chronic toxicity of adults and larvae.

European Crop Protection

"Identifying routes of exposure to pesticides should be based on available data - ranking routes by order of importance to ensure that the risk assessment focuses on the key issues of concern."

This is again indeed the case. Field and scientific data has shown that bees get in contact with pesticides following the following routes (both oral and contact):

- pollen and nectar (incl. extrafloral nectaries)
- dust
- water (incl. surface water and plant exhudates)
- honeydew
- spray

Taking into consideration the different circumstances found in real life and the biological cycle of bees and agriculture, it is impossible to generalise a ranking of routes by order of importance for Europe.

As a result, all criteria requested by pesticide industries are already included in the new methods proposed by the EFSA.

Considering this, Bee Life encourages pesticide industries to work for the wellbeing and safeguard of bees and support, instead of blocking, the implementation of the guidance document of the EFSA for the risk assessment of pesticides on bees.