Bee Life

May 2015

EFSA Guidance :
New methodologies to assess the risks of pesticides on bees

BEE LIFE
EUROPEAN BEEKEEPING COORDINATION ASBL

4, Place Croix du Sud
B-1348 Louvain-la-Neuve
Belgium

+32 10 47 34 16
info@bee-life.eu
www.beelife.eu

European Beekeeping Coordination

1. RISK ASSESSMENT OF PESTICIDES ON BEES : A LEGAL OBLIGATION

Regulation (EC) N° 1107/2009 defines the approval criteria, for the European marketing of an active pesticide substance, as follows.

*« 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. »*

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

When a plant protection company 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 various data and information. Regulations (EC) n° 283/2013 et 284/2013[2] define these data requirements. These are now more comprehensive than in the past and include data on:

- **Acute toxicity:** toxic effects on non-target organisms, such as bees, which result from a single exposure to a substance in time (or multiple exposures over a very short period, for example 24 hours). Toxic exposure can occur by ingestion or by physical contact with the substance.,
- **Chronic toxicity:** toxic effects on non-target organisms such as bees, resulting from continuous or repeated exposure over time to an active pesticide substance,
- **Effects on bee-development**
- **Sublethal effects on the bees and the colony** (e.g. effects on the social behaviour of bees and the reproductive system)
- **Exposure data:** the information needed to assess the risk from pesticides present in: nectar, pollen and water, including guttation water, dust and spray-drift in the case of seed treatments. This data is required because systemic pesticides perfuse the plant's entire structure, contaminating: flowers, nectar and pollen, as well as leaves, stem and roots. In the past, tens of thousands of bee-colonies were killed by the toxic pesticide dust generated by the machine-sowing of pesticide-coated seeds. Finally, systemic pesticides can persist in soil for several years and are also readily soluble in streams, ground -water and ponds, where they also persist. Therefore, it is also extremely important to obtain data on the toxic residues which systemic pesticides produce in the wider environment.

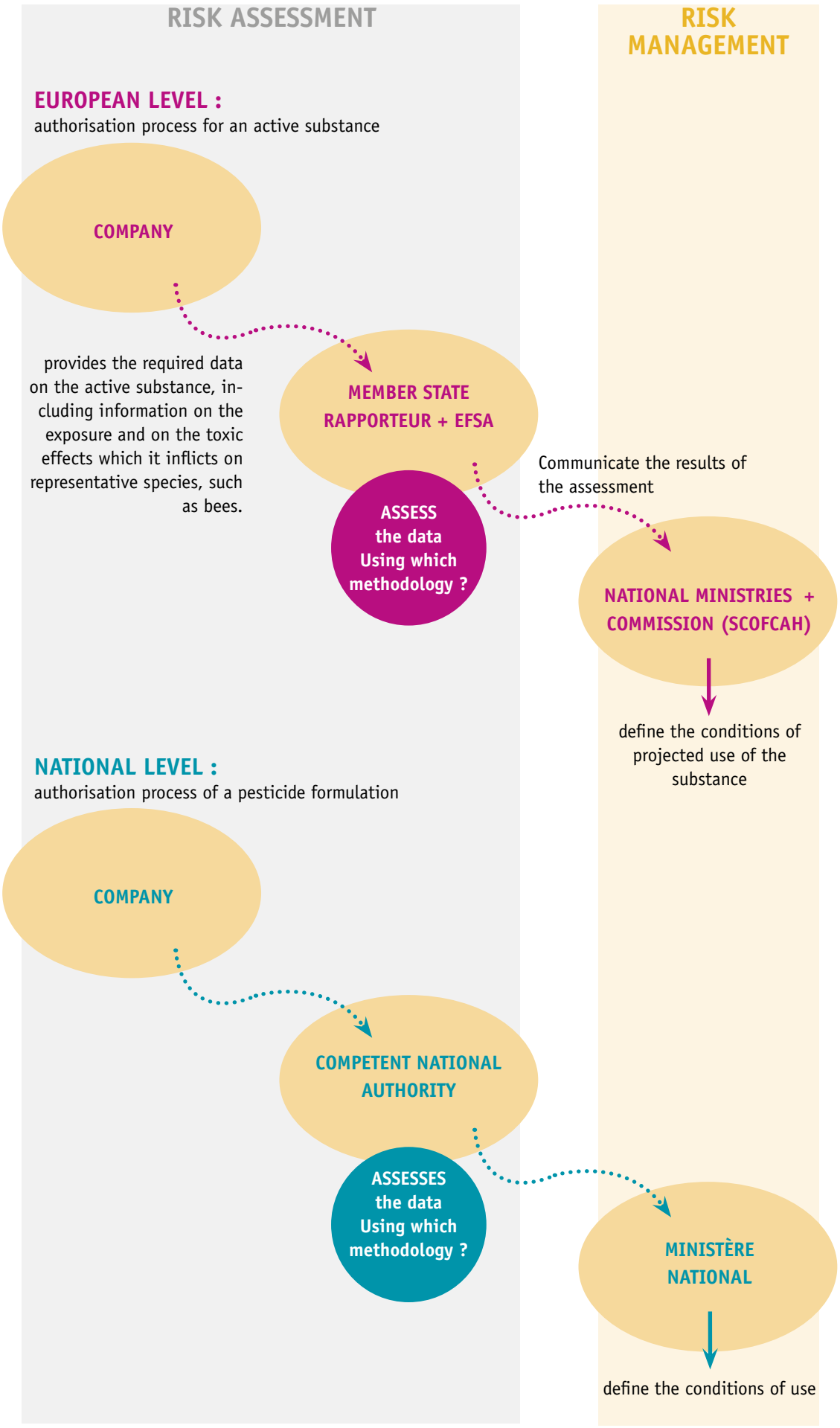
When the competent risk assessment authority (the European Food Safety Authority (EFSA) at European level and agencies or research centres at national level) receives the required data, risk assessors must analyse, interpret and evaluate the risks, which the active substance poses for bees. In order to harmonise risk evaluation among member states, the competent authorities must use standard methodologies, commonly called "Guidelines». A designated Member State, termed the 'Rapporteur', is normally given the responsibility of coordinating the production of the dossier.

The results are then communicated to the risk managers, who frame the conditions which will apply to the authorisation and marketing of the pesticide in question. The risk managers are at EU level the Standing Committee on the Food Chain and Animal Health (SCOFCAH) and at national level, the competent national ministries.
A major challenge in the above process is: how do we define the most effective guidelines for assessing the risk which pesticides pose for honeybees, bumblebees, solitary bees and other pollinators.

Water droplets expressed from some plants by foliar stomata are termed 'water guttation'. This guttation process is commonly seen on the leaves of maize and other crops.

1. *Regulation (EC) n° 1107/2009 - http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32009R1107*
2. *Regulation (EC) n° 283/2013 - http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013R0283*

Regulation (EC) n° 284/2013 - http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013R0284



Challenges and current situation regarding Pesticide Risk Assessment for bees

2. THE EFSA GUIDANCE : THE CURRENT SCIENTIFIC METHODOLOGY DEEMED MOST APPROPRIATE FOR ASSESSING PESTICIDE - RISK FOR BEES

Since 2010, the European Beekeeping Coordination has highlighted the deficiencies of the current Pesticide Risk Assessment for bees in the EU[3]. In the same year, in collaboration with Corporate Europe Observatory (CEO), the European Beekeeping Coordination also revealed that the European Commission, was 'unknowingly' devolving the expertise on risk assessment methodology to pesticide manufacturers[4], this constitutes a major conflict of interest.

In recognition of this conflict of interest, the Commission (DG SANTE) responded quickly. In 2011, the Commission asked EFSA to re-evaluate the scientific basis, on which the pesticide risk assessment for bees, is currently carried out.

As a result, in 2012, EFSA published a scientific opinion[5] which revealed major weaknesses and gaps in the current Risk Assessment Methodology. Problems included: failure to deal with chronic toxicity: sublethal effects (effects that do not cause immediate death, but which damage the normal development of bees and the colony); failure to deal with larval toxicity: various routes of toxic exposure through: water, food (pollen, nectar…) or air (seed dust,…) were not taken into account.

The resulting scientific opinion from EFSA was the basis of a new guidance document which proposed a new Risk Assessment Methodology, published in 2013; namely the « EFSA Guidance on bees[6] ».

Various public consultations were held by the Agency to strengthen this document by ensuring that the process was not not only scientifically sound, but also transparent and democratic. Currently, 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 for bees and pollinators.

	EPPO Guidelines Currently used	**EFSA Guidelines currently not approved, nor implemented**
Title	Environmental risk assessment scheme for plant protection products - PP 3/10 (3) : chapitre 10 : honeybees [7](last update, 2010)	Guidance on the risk assessment of plant protection products on bees *Apis mellifera, Bombus* spp. and solitary bees) (2013)
Authors	The Bee Protection Working Group within the International Commission for Plant-Pollinator Relationships (ICPPR) prepared the document for the European and Mediterranean Plant Protection Organization (EPPO). The pesticide industry was strongly represented within the Bee Protection Group.	An independent group of expert within EFSA
Assessment scheme	Adapted for the spraying application and short term exposure	Adapted to diverse type of exposure: through pollen, nectar, water, dust, including short and long term exposure
Study toxicology	Acute toxicity on Apis mellifera (honeybee)	Acute and chronic toxicity of larvae and adult bees Assessment of sublethal effects and cumulative toxic potential for *Apis mellifera, Bombus* and solitary bees

Comparative table between the EPPO Guidelines currently used and the new EFSA Guidelines not approved, nor implemented to date (May 2015)

3. ERA of pesticides on bees – State of play and future possibilities - http://bee-life.eu/medias/position_coeur/era-ebc-v12.pdf

4. Is the future of the bees in the hands of pesticide lobby? - http://bee-life.eu/medias/news/future-of-bees.pdf

5. Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (Apis mellifera, Bombus spp. and solitary bees) - http://www.efsa.europa.eu/en/efsajournal/pub/2668.htm

6. Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees) - http://www.efsa.europa.eu/en/efsajournal/pub/3295.htm

7. Environmental risk assessment scheme for plant protection products - PP 3/10 (3): Chapter 10: honeybees - http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2338.2010.02419.x/full http://www.eppo.int/

The EFSA Guidelines provide a Risk Assessment Methodology that would enable us to:

1) Interpret, analyse and better understand the risk which pesticides pose for bees and pollinators
2) Harmonise the assessment of these risks across all European Member States
3) Provide clearer information to policy makers, enabling better-informed decision making

Failure to adopt the new EFSA Guidelines would go against the spirit of EU legislation on pesticides. Such a backward step, would limit regulators to the continuing use of the inadequate Risk Assessment Methodologies, which were created by a group of experts close to the plant protection industry.

3. EFSA GUIDELINES ARE INAPPLICABLE FOR MEMBER STATES

Risk assessors within the European Union 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 implementation of the new Guidelines, in order to avoid the adoption of an improved and appropriate risk assessment of pesticides for bees in Europe.

The legal and the scientific bases are all in place, but this political blockage prevents adoption of the new Guidelines, due to the economic interests of Member States or lobbying by pesticides 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 very difficult to obtain detailed information on the actual position of Member States. The pesticide companies, from their side, fear that the EFSA Guidelines are going to hamper the marketing of their products and hence their profits.

8. http://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals/index_en.htm

4. THE EU COMMISSION TAKES THE LEAD ON THE DOSSIER

Since the EU Member States have failed to reach an agreement, regarding the EFSA Guidelines on bees, the document is still waiting for their approval in 2015.
In order to confront this political impasse, the EU Commission asserted its right to take the lead on the process. DG SANTE, in charge of the dossier, decided to assess the potential impact of adopting the EFSA Guidelines. This process will be supported by various services of the Commission under the Direction of the Commission Vice-President, Frans Timmermans. The objective of this internal Commission process is to present a proposal to Member States, which they would be obliged to accept and implement. However, some fear that the EFSA Guidelines could be watered-down in the course of these discussions and negotiations? DG SANTE promises that this will not happen, but the question remains.

5. OTHER STAKEHOLDERS INVOLVED

The proposed implementation of the EFSA Guidelines seems to have shaken-up the established order on pesticides regulation. For many years the pesticides companies have played a dominant role in framing and defining the Pesticide Risk Assessment Methodology for bees in Europe.
The historical strength of the pesticides lobby within the EU, is largely the reason why the current battle, over pesticide risk assessment methodologies for bees continues; not so much at the European level, but within other institutions or groups.

OECD

Firstly, there has been strong pressure from Member States, in concert with the pesticide industry, for the Organisation of Economic Cooperation and Development (OECD)[9] to develop its own methodological standards and validate the EFSA methodologies. The OECD includes countries outside the EU, such as: Canada, the USA and Japan. Among its various roles, OECD already has the development of a long list of international methodological standards to its credit. However, the representation of industry is 'institutionalized' within the OECD, through the BIAC[10] participation. This means that pesticide companies have considerable leverage to influence any work developed by the OECD.

ICPPR

The Bee Protection working group within the ICPPR[11] has begun work to validate the tests on Bombus (bumblebee species) and solitary bees, proposed by EFSA. The pesticide industry continues to be strongly represented in this working group.

APITOX

In the light of the conflict of interest which exists in relation to the 'bee and pesticide' issue, a group of independent scientists, has created a working group within COLOSS[12] called APITOX; this group intends to analyse the proposed EFSA methodology and provide answers to specific questions which remain unresolved.

9. *http://www.oecd.org*
10. *http://biac.org*
11. *http://www.uoguelph.ca/icpbr/index.html*
12. *http://www.coloss.org*