

POLLINIS

A NOT-FOR-PROFIT NGO REGISTERED UNDER FRENCH LAW, POLLINIS IS FUNDED EXCLUSIVELY BY DONATIONS FROM INDIVIDUALS TO PROTECT WILD AND HONEY BEES, AND TO PROMOTE SUSTAINABLE AGRICULTURE IN ORDER TO HELP PRESERVE POLLINATORS.



RISK ASSESSMENT OF PESTICIDES ON POLLINATORS IN EUROPE: OBSOLETE PROCEDURES AND CONFLICTS OF INTEREST

A brief history of the EFSA Guidance Document

SYNOPSIS

Europe faces a massive decline of pollinators. Urgent measures have to be adopted to hamper this decline. A proper evaluation of the impact of pesticides on non-targeted species is of paramount importance in this context. However, current pesticide risk assessment procedures for pollinators are still not harmonised at the European Union level and follow outdated guidelines, which neither allow for an efficient evaluation of the new generation of pesticides nor comply with regulations for pesticide approval presently in force. In 2013, the European Food Safety Authority (EFSA) produced newer guidelines, in line with the present regulatory framework, the Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees), hereinafter the EFSA GD. However, its adoption at the EU level has been blocked ever since by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF).

Being aware of the importance of a proper risk assessment on pollinators, the European Commission launched a new implementation plan of the EFSA GD in June 2018. But again, SCoPAFF blocked it. The total lack of transparency surrounding this Committee prevents citizens from identifying the reasons and the Member States behind the blockage. All the documents concerning the SCoPAFF decision-making process are off-limits, allegedly to “*protect the decision-making process*” itself. But civil society associations are concerned about the delay of this process (more than five years), which is beyond a reasonable time limit.

INTRODUCTION

POLLINATORS ARMAGEDDON

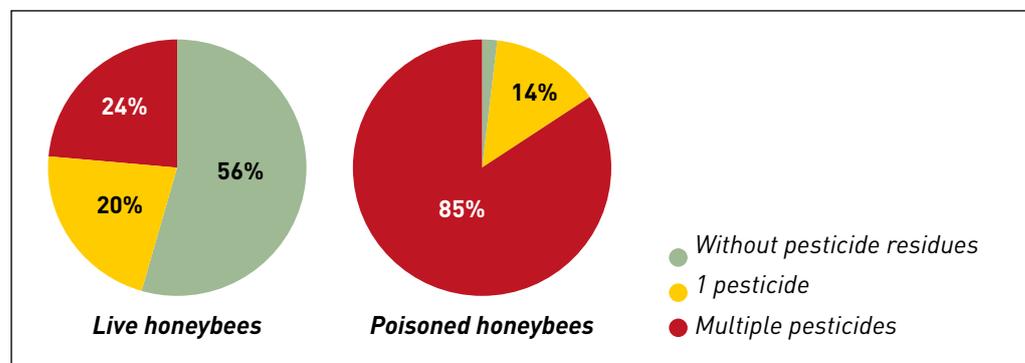
→ Testing the true impact of pesticides on bees

Europe faces a massive decline of insects: more than 75% of flying insects have disappeared from German protected areas (Hallmann *et al.* 2017). According to the authors of the study, this finding can be extended to the entire European territory. Pollinating insects are particularly in danger: behind the well-documented phenomenon of domestic bee losses lies a problem of a much larger scale, namely “*the dramatic decline in the occurrence and diversity of all kinds of European wild insect pollinators, including wild bees, hoverflies, butterflies and moths. Numerous pollinator species are extinct or threatened with extinction*”, according to the data published by the European Commission (EC) in 2018.

This dramatic decline is to have serious consequences on food security. In the European Union (EU), around 84 % of crop species and 78 % of wild flower species depend, at least in part, on animal pollination; up to almost 15 billion euros of the EU’s annual agricultural output is directly attributed to insect pollinators (EC 2018).

The decline of pollinators is also a matter of serious concern for biodiversity, which triggers a chain reaction in the overall ecosystem. As recent studies have reported, common birds are declining at an appalling rate in Europe (Inger *et al.* 2014); in France, one third of the bird population has disappeared from rural areas in the last 15 years, due to insect deaths (MNHN 2018).

It is therefore essential to implement urgent measures to halt this decline, as recently highlighted by the EC with its Pollinators Initiative. One of the main causes of this decline is the intensive use of pesticides (Plant Protection Products - PPPs)¹: indeed, exposure to toxic pesticides is a major cause of pollinator mortality. A recent toxicological analysis of selected samples of dead honeybees in Europe showed that 98% of the dead bees examined were poisoned by multiple pesticide residues (Kiljanek *et al.* 2017).



PART I

PLACING PESTICIDES ON THE MARKET

→ An ambitious EU regulation

In 2009, following the growing scientific evidence of the negative impact of plant protection products on human health and the environment, the EU adopted an ambitious Regulation (EC No 1107/2009)², to oversee the placing on the market of pesticides. This regulation sets the protection of human health and of the environment as a founding principle, introducing new criteria for the evaluation of PPPs. This led to a significant number of new obligations for studies submitted by firms as part of their application dossier for the approval of a pesticide (both active substance and formulation).

These obligations are detailed in Regulations (EU) 283/2013 and 284/2013, concerning the authorization of active substances and PPPs respectively, which list around 20 new data requirements, almost all of them in the environmental and ecotoxicological chapters³ (EPRS 2018: II-42).

Concerning pollinators (only bee species), in addition to data on acute toxicity⁴, the new requirements notably include data on:

- chronic toxicity to bees (honeybees, bumblebees and solitary bees);
- the effects on honeybee development and other honeybee life stages;
- pollen and bee products;
- dust drift;
- water, including guttation⁵.

¹ The term "pesticides" refers to substances used to suppress, eradicate and prevent organisms that are considered harmful. They include biocidal products and plant protection products.

² According to Regulation (EC) No 1107/2009, an active substance, a safener or a synergist can only be approved if it is established that its use will result in 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 behavior (Point 3.8.3, annex II, Procedure and criteria for the approval of active substances, safeners and synergists pursuant to Chapter II, regulation (EC) No 1107/2009).

³ See European Implementation Assessment, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market.

⁴ Already foreseen by the previous legal framework (Directive EC 91/414).

⁵ See Appendices of both regulations (Point 8.3.1 of Regulation (EU) 283/2013 and 10.3.1 of Regulation (EU) 284/2013). Commission Communications in the framework of the implementation of Commission Regulations (EU) No 283/2013, No 284/2013 of 1 March 2013 setting out data requirements for active substances/plant protection products.

Data on sub-lethal effects (such as behavioural and reproductive effects) can also be required⁶.

These studies need to be conducted according to specific guidelines, in order to allow relevant authorities to:

1. Verify their exhaustiveness and methodology.
2. Provide all the relevant data to properly assess the risk of pesticides and their metabolites on bees.
3. Guarantee the respect of the Specific Protection Goals⁷.

→ An obsolete and inefficient risk assessment scheme

However, at the time of the promulgation of Regulations 283 and 284 (2013), the available risk assessment scheme⁸, defined in 2002 under the old directive on pesticides (91/414/EEC), which dates from 1991, did not comply with the approval criteria and data requirements established by the new legal framework, which imposes higher requirements for bees. The section on bees, which lists the standard tests as defined by the European and Mediterranean Plant Protection Organization (EPPO)⁹, was revised in 2010 with the International Commission for Plant-Pollinator Relationship (ICPPR) recommendations, but this revision proved inadequate (Simon n.d.: 9 ff.). In addition to the absence of protocols to produce all newly required data, this assessment scheme is problematic for several other reasons:

- it is outdated and cannot properly evaluate the risks of the new generation of pesticides, such as systemic pesticides;
- it shows several weaknesses in its methodology (laboratory, semi-field and field tests) (EFSA PPR 2012: 48-100);
- it provides evaluation protocols on honeybees only, thus failing to identify potential effects on non-Apis bees (bumblebees and solitary bees) (EFSA PPR 2012: 48).

→ The shadow of conflicts of interest

Since 2010, members of the European Parliament and beekeeper associations have been expressing their concern to the Commission as to the appropriateness of this risk assessment scheme, and in particular on the EPPO test methods (EFSA 2013: 6). Indeed, EPPO test methods are based on the proposal of the Bee protection group of the ICPPR¹⁰, an expert group whose conflicts of interest have been highlighted several times since 2007¹¹. It is enough here to mention that the meetings and symposia of ICPPR are sponsored by the agrochemical industry¹², and that several of the ICPPR

⁶ "Tests investigating sub-lethal effects, such as behavioural and reproductive effects, on bees and, where applicable, on colonies may be required" (Regulation EU 284/2013: point 10.3.1.4/5).

⁷ Regulation EC 1107/2009 concerning the placing of plant protection products on the market broadly describes general protection goals under Chapter II, Article 4.3 (complementary criteria for the residues of pesticides are in Article 4.2). For a detailed definition of the Specific Protection Goals in the context of pesticides regulation and ecosystem services, see EFSA PPR 2012: 9-26.

⁸ SANCO guidance document on terrestrial ecotoxicology - SANCO/10329/2002 (see EC 2002).

⁹ Chapter 10: honey bees" (EPPO/OEPP, 2010).

¹⁰ Formerly International Commission for Plant-Bee Relationship.

¹¹ For a detailed analysis of ICPPR conflicts of interest, see Muilerman 2018.

¹² For instance, the 2017 ICPPR symposium in Valencia, was sponsored by Bayer; its 10th Symposium, held in Bucharest in 2008, was sponsored by : BASF Ag, Bayer CropScience AG, Dow AgroSciences, E.I. Dupont de Nemours, Syngenta Ltd. (pub.jki.bund.de/index.php/JKA/article/download/116/102). See also Muilerman 2018.

bee-experts involved in the production of the EPP0 document had close connections with the main pesticide producers or were indeed industry staff¹³.

PART II

THE EFSA DOCUMENT: GOOD GUIDANCE UNDER A 5-YEAR LONG BOYCOTT

To address these concerns, and to provide a more comprehensive risk assessment scheme in line with the new regulations, the EC mandated the European Food Safety Authority (EFSA) to develop a Guidance Document (GD) on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA 2014), the EFSA GD, conceived to provide proper guidance for notifiers and authorities in the context of the review of PPPs and their active substances under Regulation (EC) 1107/2009.

→ The most appropriate methodology to date

EFSA published a first version of the GD in 2013 that was revised in 2014 (EFSA 2014). For the first time in Europe, the EFSA GD provided appropriate and comprehensive test guidelines to assess the effective impact of pesticides on bees (honey bees, bumblebees and solitary bees), based on available experimental evidence and scientific research. The EFSA GD proposes a three-tier risk assessment approach, beginning with laboratory tests (first tier) and, if the latter indicate a potential risk, proceeding with semi-field (second tier) and field tests (third tier). These guidelines represent an updating of the previous assessment scheme, which in the first tier only required the study of acute risks for honeybees, whereas the EFSA document also requires a chronic risk analysis for honeybees and larvae, as well as a risk assessment for bumblebees (acute toxicity) and solitary bees.

It is worth noting that the overall scientific process of producing the GD has been conceived to include, besides the scientific opinion of an ad hoc panel of experts (EFSA 2012), the output of independent studies, through a review of the independent scientific literature and the organization of public consultations.

For these reasons, as of today, the EFSA GD can be considered as:

1. the most comprehensive, though not exhaustive, tool allowing to assess the risks of PPPs on different bee species (honey bees, bumble bees, solitary bees);
2. the best-suited methodology available to evaluate the risks posed by systemic pesticides;
3. the most transparent and science-based guidance document.

In this sense, the EFSA GD represents a very good first step toward a comprehensive risk assessment scheme taking into consideration the real impact of pesticides on all pollinators in general, not only bees.

¹³ On the three working groups on bees, six experts over 17 belonged to the industrial sector: Roland Becker (BASF), Mike Coulson (Syngenta), Nathalie Ruddle (Syngenta), Ed Pilling (Syngenta), Christian Maus (Bayer Crop Science) et Mark Miles (Dow Chemicals) (Muilerman 2018: 46).

→ The comitology blockage

However, despite such an approach (i.e. combining a strong scientific background with transparency and exhaustiveness) the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), composed of representatives of Member States and presided over by a EC representative, has not yet to date taken note of the EFSA GD, even though this committee was consulted beforehand by EFSA to define the protection goals to be achieved. **The SCoPAFF obstruction means that the new GD has not been endorsed at the EU level, and that there is no harmonisation of assessment schemes among Member States¹⁴.**

POLLINIS does not know the exact reasons for this lack of endorsement: when questioned on this issue, the Commission's response was that, in accordance with Regulation (EC) No 1049/2001, this information was confidential¹⁵, in order "to guarantee the protection of the decision-making process" (a decision-making process that has been inconclusive for five years).

At the same time, however, Regulation (EC) No 1049/2001 also specifies that the confidentiality rule does not apply in matters involving an overriding public interest¹⁶. In our opinion, the reasons as to an updated risk assessment scheme to prevent chemical substances dangerous to pollinators from accessing the European market and to curb an insect armageddon in Europe is repeatedly not endorsed, *are* matters of public interest.

Sadly, this is not the opinion of the EC Directorate-General for Health and Food Safety, which considered that: "*there is no evidence of an overriding public interest in disclosure [of the documents requested by POLLINIS]. The public interest in this case is rather to protect the Commission's decision-making process.*" (see letter attached, Appendix 1). Apparently, transparency in the EU ends where comitology begins. This provides a good example of reasons why European civil society may feel that the EU institutions defend corporate interests rather than those of the common people and the environment.

→ Science meets politics

One may also wonder why scientific guidelines for risk assessments need to be approved by SCoPAFF at all, considering that this Committee has already participated in the definition of the protection goals to be achieved. With other regulatory sectors, EFSA can formulate and adopt risk assessment criteria and guidelines whose applications do not require a political vote in comitology (EPRS 2018: II-7).

¹⁴ In such a methodological vacuum, EFSA has recommended the following temporary risk assessment approach: "it was acknowledged that the risk assessment scheme currently in place in European Commission (2002) is not sufficient as does not cover the new data requirements. EFSA suggested that specific concerns (i.e. based on a.s. case specific studies) could be further discussed in dedicated experts' meetings. Overall, in the absence of alternative approaches taken note by risk managers, it was recommended that the risk assessment to honeybees should be performed (first tier) according to EFSA (2013). For higher tier, the studies should be critically evaluated and considered in light of the issues raised in EFSA PPR Panel (2012) and EFSA (2013) with regard to the methodologies used." (EFSA 2015: 12). Indeed, most Member States don't follow these recommendations : see for instance Germany (https://www.bvl.bund.de/EN/04_PlantProtectionProducts/03_Applicants/04_AuthorisationProcedure/08_Environment/ppp_bee_protection_basepage.html) which is still indicating the EPPo methodology.

¹⁵ More precisely, out of the 29 documents identified by the EC falling under the scope of our request, we were only given access to two documents: an invitation to a workshop and the questionnaire to be refunded for travel expenses for the same workshop (see Appendix 2). The 27 others were allegedly covered by the confidentiality rule.

¹⁶ It specifies: "Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure." (Regulation EC No 1049/2001, article 4(3), first indent).

Indeed, the division between 1) the scientific assessment of the risk involved in the use of a chemical product and 2) the political management of such a risk, i.e. the separation of the evaluation phase from the decision phase, is another founding principle of the risk assessment approach of the European legal framework concerning pesticides. It is the very *raison d'être* of EFSA: EFSA's Founding Regulation (EC) No 178/2002 introduced the functional separation of risk assessment and risk management and enshrined the interrelated core values of independence, scientific excellence, transparency, and openness¹⁷. Thus, based on the information provided by the risk assessment carried out by the EFSA, risk managers (EU members states and EU Commission together) decide whether or not the active component of a pesticide can be authorized in the EU market.

But, when considering SCoPAFF's obstruction to a scientific guidance document, it is worth asking if such a functional separation is not blurred in practice, with the risk management level actually preventing the adoption of a scientific method of evaluation of risks. The solution to this problem may be to depoliticize this document and leave to science alone the authority to decide on its appropriateness, as recently suggested by the EC Health and Food Safety Commissioner, Vytenis Andriukaitis¹⁸.

Being convinced that the European citizens have the right to know, POLLINIS asked the European Ombudsman to address these different concerns in September 2018, and to clarify if:

- the delay of the adoption of the EFSA GD is a matter of public interest;
- the role of SCoPAFF in approving scientific guidelines is blurring the institutional division between risk evaluation and risk management;
- the length of the SCoPAFF decision-making process has exceeded a reasonable time limit.



¹⁷ The regulation that lays down the principles for the establishment of EFSA (178/2002, art. 6.2) states: "Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner".

¹⁸ Special Committee on the Union's authorisation procedure for pesticides (PEST), Public Hearing on EU authorisation procedure for pesticides - Commission approval of active substances, 19 June 2018. <http://www.europarl.europa.eu/ep-live/en/committees/video?event=20180619-1500-COMMITTEE-PEST>

THE MEMBER STATES AND THE AGROCHEMICAL LOBBY

Although the reasons why SCoPAFF refused to take note of the EFSA GD remain confidential, we do know, however, that the European Crop Protection Association (ECPA), the association representing the agrochemical industry in Europe, is strongly opposing the adoption of this document. ECPA is constantly trying to influence SCoPAFF to reject the adoption of the EFSA GD. As one of the letters addressed by this association to members of this committee says: *“ECPA will continue to ask that the Commission, EFSA and Member States not to adopt the guidance document as it currently stands, on the basis that it is not fit for purpose and does not provide useful support to decision-making”* (see Appendix 2).

On the contrary, the GD requirements fit its purpose and provide useful support to decision-making as demonstrated, for instance, by EFSA’s recent reports (since 2016); in particular those assessing the impact of three neonicotinoids (thiametoxam, clothianidine, imidacloprid) on bees. These reports were based on the GD and led to the ban of the same three molecules in the EU (EFSA 2018).

Another criticism addressed by the agrochemical industry to the EFSA GD is that *“[m]any of the laboratory test methods required by the guidance document were either not available or not fully developed for regulatory purposes”* (ECPA 2017). That was the case in 2013, at the time of the GD publication. However, in the meantime, several of these test methods have been developed (mainly by the OECD) and are at present available or in the last stages of experimentation (ring tests). For this reason, rather than rejecting the EFSA GD, it would be enough to update it with the new available test methods.

Indeed, this is exactly what Belgian authorities did to develop their national approach, adopting the EFSA GD and updating it with the latest OECD test methods for risk assessment on bees (see Appendix 3) (FPS 2018). It should be stressed that, at present, the EFSA GD not only needs to be updated and ideally improved to take into account other potential sources of risk (e.g. non intentional pesticide mixtures, among others) but also include other pollinator species.

→ The agrochemical industry and its own risk assessment scheme

But ECPA is apparently not interested in such an updated version of the EFSA document: what the industry is requesting from European institutions and Member States is a *“significant revision of the... EFSA GD before any type of implementation”* (see Appendix 4). This significant revision should in fact reflect the “bee pollinators risk assessment” scheme developed by the industry itself. Indeed, since 2013, ECPA is promoting a “proposal for a practical approach” (ECPA 2017) for risk assessment on pollinators. As specified in the ECPA document presenting such a risk assessment scheme, *“[k]ey features of this approach are the focus on honey bees as a representative species, the definition of*

core data packages, concentration on main exposure routes and the proposal of more realistic assumptions for the risk assessment process” (ECPA 2017). Now, when one looks more closely at what ECPA means by these “more realistic assumptions for the risk assessment process”, one finds that it is mainly a matter of “protection goals”, exposure levels and trigger values (a trigger value defines a level above which risks for human health or the environment cannot be waived a priori) (Wagner 2017). Indeed, the ECPA document adopts a tolerance limit of 20% (ECPA 2017): in other words, it considers that a product killing up to 20% of bee colonies is safe for bees, whereas the EFSA GD establishes this same limit at 7% (EFSA GD 2014: 12). ECPA’s focus on honey bees as a representative species is also questionable, if we consider that “the effect of pesticides in domestic and wild bees is dependent on the intrinsic sensitivity of single bee species as well as their specific life cycle, nesting activity and foraging behaviour. Current data indicates a need for (...) separate pesticide risk assessment procedures for non-Apis bees” (Arena and Sgolastra 2014).

In addition to the above-mentioned scientific and methodological considerations which show the inadequacy of ECPA’s proposed approach in guaranteeing a high level of protection for bees and pollinators in general, it should also be underlined that, from a juridical point of view, a risk assessment evaluation based on a protocol produced by the industry is a major distortion of the “producer pays” principle, one of the structuring principles of the European risk assessment system. According to this principle, the burden of proving that a pesticide is not harmful lies on the producer (i.e. the firm demanding a marketing authorization, which will benefit from its commercialization). This is why EFSA bases its scientific conclusions mainly on studies sponsored and in many cases carried out by the industry itself on its own products.

Of course, to provide a useful support for the evaluation and the decision-making processes, these studies must be conducted according to specific protocols, which translate the protection goals established by the competent authorities into precise data requirements.

But what happens when the industry itself can set its own data requirements?

→ Safe or not safe: should the firms decide?

In this case, the industry not only conducts the studies needed to assess the risk of a PPP for human health and the environment, but also establishes the criteria for evaluating the potential risk of its products. Thus, the industry may exclude, for instance, substances that do not directly target insects (such as fungicides and herbicides), or may state that a product can be considered “safe” for bees even if it kills up to 20 % of the colony, or may decide to ignore non-Apis species. In short, the industry is allowed to decide what is dangerous and what is not, thus, ultimately, redefining the very protection goals that our juridical framework is supposed to enforce. This is a major conflict of interest.

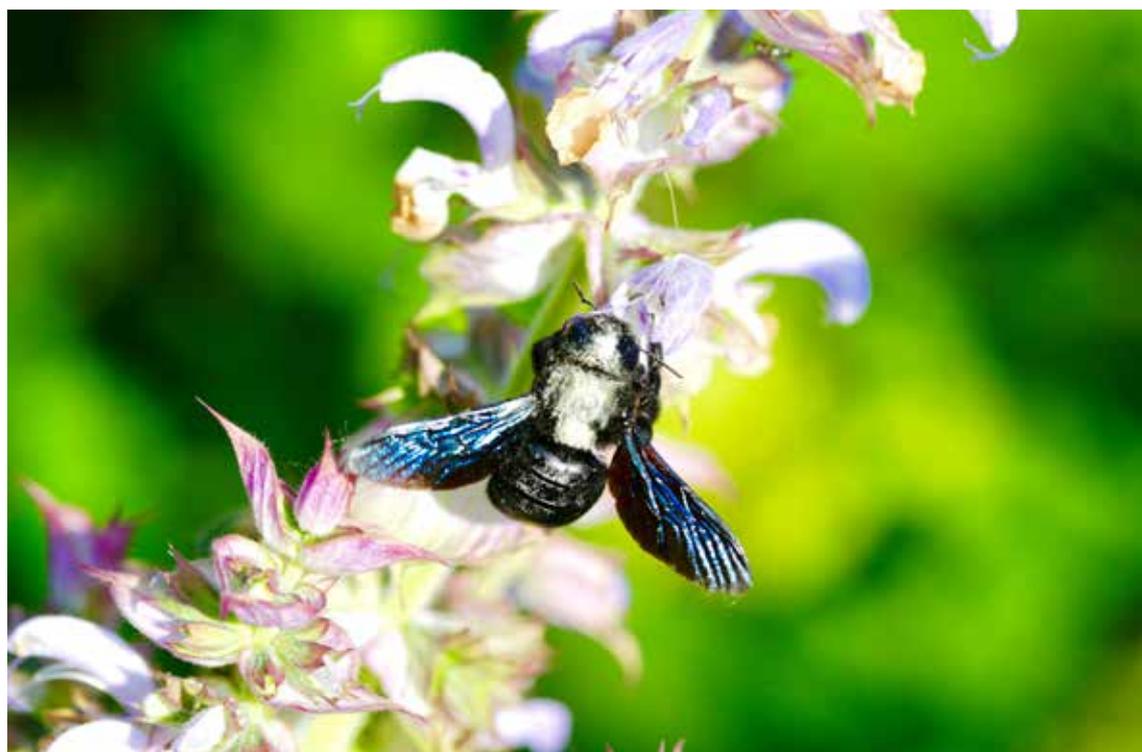
It is important to stress that the risk assessment process is primarily a matter of data requirements: if these are not in line with the preservation principles established by the law, then even the most ambitious juridical framework in the world will prove useless to guarantee the protection goals that it enshrines.

Thus, the establishment of specific guidelines for risk assessment methodologies has an enormous strategic value and should rest on independent science and concerned authorities, not on corporate interest groups such as ECPA, which, by definition, are protecting the interests of the industrial sector and not those of the environment.

→ The European Commission agenda

The EC recently decided to relaunch the implementation plan of the EFSA GD (EC 2018) through a stepwise approach: the first tier by the end 2018 and the higher tiers at a later date.

However, the EC already launched a similar implementation plan in 2014¹⁹ which was not successful because (as said earlier) of SCoPAFF's opposition. Thus, nothing prevents a further failure if the SCoPAFF position does not change. Indeed, SCoPAFF meetings on 23-24 October and 12-13 December 2018 already asserted that it would not endorse the entire first tier. It is likely that it will eventually accept a shorter adaptation including only guidelines for acute toxicity and only limited to honeybees. In this case, not only will the risk on bumblebees and solitary bees not be evaluated at all, but tests on chronic toxicity will not be included either. Now we know that for the new generation of pesticides, the evaluation of the lethal or sublethal effects of chronic exposure is of paramount importance.



¹⁹ See DRAFT Implementation plan for the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees), 16 May 2014, SANCO/10606/2014.

WHY CHRONICITY TESTS MATTER

The new generation of pesticides with a systemic application shows several differences when compared to older pesticides that were usually sprayed externally on plants. The latter could contaminate neighbouring crops if the spray drifted in the wind, and although this could be particularly dangerous in terms of acute toxicity, this toxicity usually disappears within days. Systemic pesticides, on the contrary, can migrate into other untreated crops and wildflowers, which are far away from the fields where they are applied; they can also persist for years in the environment. Clothianidin, for instance, has a half life of 19 years in clay soils (Simon n.d.: 4).

Thus, the exposure patterns and toxic effects of systemic pesticides are radically different from those of spray pesticides: for systemic pesticides, the exposition may occur at lower doses but be prolonged in time and expanded in space. Exposure can even occur in the hives themselves through the residues present in pollen and bee' products. Also, exposure has different impacts according to different insects' life-stages.

These new patterns of exposure (at low doses but prolonged in time) constitute an essential aspect for the evaluation of systemic pesticides. This is why, besides acute toxicity, the EFSA GD introduces other important parameters in its first tier to properly evaluate the risk of systemic pesticides for bees:

1. chronic toxicity to assess longer exposure in time and accumulation effects;
2. multiple exposure routes in food (pollen, nectar, honeydew), water (guttation water, surface water) and habitat (soil, dust, etc.);
3. effects on different life stages of bees and effects likely to affect the whole colony (for honey bees).

These parameters, including the evaluation on chronic toxicity, are of paramount importance: no risk assessment can be accurate if they are not taken into consideration.

On the other hand, when these parameters are taken into consideration, they change the picture: for instance, the toxicity for pollinators of the three neonicotinoid molecules (thiametoxam, clothianidine, imidacloprid) recently banned in the EU, could be detected and measured thanks to the protocols indicated by the EFSA GD.

So why not adopt these much needed tests on chronic toxicity?

The agrochemical industry in its "impact analysis" of the EFSA GD gives a quite clear answer to this question: because most of the pesticides present on the EU market today would not pass this test (first tier) (Miles *et al.* 2018).

These claims are based on an evaluation, conducted by the main pesticide producers (Bayer, BASF...), of the "*pass/fail rate of currently available active substances on the EU market*" if these substances were to be assessed following the EFSA GD (Miles *et al.* 2018: 87). This study shows in particular that the pass/fail rate according the EFSA GD for acute risk was similar to the current risk assessment outcomes, but that a significant difference was observed for the chronic toxicity tests (Miles *et al.* 2018: 87-8). In this case, "**79% of all herbicide uses failed as well as 75% of fungicide uses and all 92% of insecticide uses.**" (Miles *et al.* 2018: 88).

If, from the market-oriented point of view of the industry, the outcomes of the chronic toxicity tests indicate that the EFSA GD is “*unworkable in its present form*” and “*a danger for innovation*” (Miles *et al.* 2018: 89), from the citizens’ point of view these same outcomes indicate that most of the PPPs currently on the market are a danger for pollinators. In other words, these outcomes point to additional evidence to the deficiency of the current risk assessment in place; and also highlights the urgency of adopting the efsA Gd in its entirety, i.e. including the chronic toxicity tests and higher tiers.

These tests can make a difference in the protection of pollinators in Europe. Unfortunately, it is likely that, at its next meeting in January 2019, SCoPAFF will again block the adoption of the EFSA GD, or even the adoption of its first tier including chronic toxicity tests. Such a position will postpone the protection of pollinators for a dangerously long time in the EU.

Civil society is wondering why SCoPAFF, a Committee that is supposed to represent Member States governments and thus EU citizens, is repeatedly hindering a decisive step for pollinator protection. As we have seen, these reasons remain confidential, allegedly to protect the decision-making process.

But how long can SCoPAFF keep such a decision-making process behind closed doors and not accountable to the citizenry it is supposed to represent? The adoption of the EFSA GD has been discussed at least 20 times by SCoPAFF since 2013 (See Appendix 5). We find that such a decision-making process has already exceeded any reasonable time limit: pollinators are disappearing at an appalling rate. We cannot wait anymore.

RECOMMENDATIONS

Data requirements are the cornerstone upon which the overall risk assessment system is based.

It is clear that the risk assessment scheme currently in place neither complies with the present legal framework nor guarantees an adequate evaluation of the risk of PPPs on pollinators.

As a matter of fact, the European evaluation of risks posed by PPPs on bees is still conducted according to obsolete procedures, produced by institutions, like ICPPR, with a record of demonstrated conflicts of interest. These procedures do not comply with the present legal framework and their limited assessment range does not take into account relevant data even when they already exist, which is illogical if the real goal is to protect non-targeted species. As specified in the Belgian plan: *“from a scientific point of view, it is not acceptable to ignore available robust toxicity data on vulnerable non-target species simply because there is no generally accepted risk assessment guideline”* (FPS 2018: 5).

To date, only the EFSA GD takes into account all the criteria established by the European juridical framework for a proper pesticide risk assessment on honeybees, bumblebees and solitary bees. Also, this is the most complete methodology capable of evaluating the risks posed by the new generation of pesticides (e.g. systemic pesticides).

Furthermore, the EFSA GD’s overall drafting process guarantees transparency and independent science-based content, free from conflicts of interest, which is a crucial element for efficient environmental risk assessment procedures.

We consider that the adoption of this document, updated with the latest available tests and scientific findings, is absolutely necessary to properly address the question of the dangerousness of PPPs for bees, and thus essential to ensure the protection of pollinating insects in Europe.

We therefore ask the European Commission and Member States to adopt all the necessary measures in order to:

- Support the immediate implementation of the whole EFSA GD.
- Mandate EFSA to update this document with the latest available protocols, as well as to encourage research activities to address existing gaps. In the future, the EFSA GD should be improved to take into account other potential sources of risk (e.g. non intentional pesticide mixtures) as well as other pollinator species.
- Shed light on the reasons and potential vested interests that continue to delay the application of these protocols. It should be recognized by EU authorities that this is a matter of overriding public interest.

CONCLUSION

- Address SCoPAFF's lack of transparency, as well as the appropriateness of its role in endorsing the EFSA GD, a scientific document conceived to guide data collection and analysis.
- Strongly oppose any assessment scheme that is not based on independent research and the principle of transparency.
- Conceive and suggest measures to prevent any institution flawed by conflicts of interest to dictate assessment procedures and protection goals.
- Reassert that the definition of the scientific basis according to which studies need to be conducted pertains to EFSA, which also has the duty to include all the available scientific findings in its risk assessments.
- Ensure that risk managers consider ALL pertinent data before taking a decision.

- Arena, M. and F. Sgolastra (2014). «A meta-analysis comparing the sensitivity of bees to pesticides.» *Ecotoxicology* 23: 324-334.
https://www.researchgate.net/publication/259770652_A_meta-analysis_comparing_the_sensitivity_of_bees_to_pesticides [accessed Jul 04 2018]
- Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91 /414 /EEC).
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LIST OF APPENDICES

1. Answer from Directorate-General for Health and Food Safety to a request of documents mentioning the EFSA GD.
2. Letter (March 2017) from ECPA to SCoPAFF members.
3. Mandatory and optional tests of the Belgian approach (table).
4. Letter (December 2018) from ECPA to SCoPAFF members.
5. SCoPAFF agenda mentioning the EFSA GD (2013-2018).

APPENDIX 1



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/E4/AS(2018)2311209

**By registered mail with
acknowledgment of receipt**
Ms Clémentine Bonvarlet
POLLINIS
10, rue Saint Marc
75002 Paris
France

Advance copy by e-mail:
ask+request-5269-b631ab11@askaheeu.org

Dear Ms Bonvarlet,

Subject: Your application for access to documents – Ref. GestDem 2018/1680

We refer to your email dated 20 March 2018 registered on the same date with the above mentioned reference number, by which you request access to documents on the basis of Regulation (EC) No 1049/2001¹.

1. Scope of your request

In your request, you asked access on the basis of Regulation (EC) No 1049/2001 to:

"all correspondance (including emails), agendas, minutes of meetings and any other reports of such meetings between officials/representatives/Commissioner/cabinet member of DG SANTE and the members of the Standing Committee on Plants, Animals, Food and Feed, regarding EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)"

In our letter of 28 March 2018 registered as Ares(2018)1783594, we invited you to specify the scope of your request. In reply to our letter, with email of 3 April 2018, you clarified your request asking access to the above mentioned documents written between July 2013 and April 2018.

¹ Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

2. Identification and assessment of the concerned documents

We have identified 29 documents falling under the scope of your request.

Having examined these documents, we have come to the conclusion that some of the documents may be only partially disclosed as their full disclosure is prevented by two of the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001.

In particular:

- i. partial access can be granted to 2 documents that are indicated with "Partial" in the list of documents and numbered 1 and 2;
- ii. 26 documents numbered 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28 and 29 and indicated with "No" in the list of documents are protected in their entirety.

We would like to inform you that the agendas and summary reports from all Standing Committees on Plants, Animals, Food and Feed are available online at the following Commission webpage:

https://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals_en.

The documents that can be partially released and the list of documents containing the result of the assessment carried out on their content on the basis of Regulation (EC) No 1049/2001 are published on the following Commission webpage:

<https://webgate.ec.europa.eu/dyna/extdoc>

You can view these documents by entering the GestDem reference of your request ("2018/1680") in the search box at the top of the page.

Alternatively, you can click on "view documents per request" and search on the left column for the GestDem reference of your request ("2018/1680").

You may re-use Commission documents free of charge for non-commercial and commercial purposes provided that the source is acknowledged, that you do not distort the original meaning or message of the documents.

3. Reasons for refusal

- *Protection of the privacy and integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data - Article 4(1)(b) of Regulation (EC) No 1049/2001.*

Documents 1 and 2 contain personal data, such as the names of staff of the Commission and third parties. Pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access to a document has to be refused if its disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with EU legislation regarding the protection of personal data. The applicable legislation in this field is Regulation (EC) No 45/2001².

² Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable.³ According to Article 8(b) of this Regulation, personal data shall only be transferred to recipients if they establish the necessity of having the data transferred to them and if there is no reason to assume that the legitimate rights of the persons concerned might be prejudiced.

We consider that, with the information available, the necessity of disclosing the aforementioned personal data to you has not been established and that it cannot be assumed that such disclosure would not prejudice the legitimate rights of the persons concerned. Therefore, partial access is granted to the requested documents, expunged of personal data.

- *Protection of the decision-making process in accordance with Article 4(3), first indent, of Regulation (EC) No 1049/2001.*

Member States have to date not taken note of the EFSA Guidance Document on the risk assessment of plant protection products on bees in the framework of the Standing Committees on Plants, Animals, Food and Feed. The decision-making process is therefore currently fully open and ongoing.

Document 3 is the Summary report from a Workshop organised in December 2013 on the EFSA Guidance Document on the risk assessment of plant protection products on bees. Member States representatives were present at the Workshop and the Summary report contains information on the positions of individual Member States.

Documents 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28 and 29 contains comments submitted by individual Member States on the EFSA Guidance Document on the risk assessment of plant protection products on bees. This information is protected as it has been gathered in the framework of the Standing Committees, where the Guidance document has been discussed on several occasions.

The Standard Rules of Procedures for the Standing Committees⁴, which the Commission adopted pursuant to Article 9 of Regulation (EC) No 182/2001⁵, explicitly exclude the positions of individual Member States from public access. In fact, Articles 10(2) and 13(2) of the Standard Rules of Procedure affirm, respectively, that summary records of the meetings shall not mention the position of individual Member States in the committee's discussions and that the committee's discussions shall be confidential.

It follows that the Commission cannot grant public access under Regulation (EC) No 1049/2001⁶ to documents containing references to the individual Member States that expressed opinion in the framework of committee meetings, as this would result in the above-mentioned confidentiality requirement being deprived of its meaningful effect.

³ Judgment of the Court of Justice of the EU of 29 June 2010 in case C-28/08 P. Commission/The Bavarian Lager Co. Ltd, ECR 2010 I-06055.

⁴ OJ C 206, 12.7.2011, p. 11.

⁵ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, p. 13.

⁶ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.05.2001, p. 43.

In its *Corporate Europe Observatory* judgment⁷, the General Court confirmed that minutes circulated to participants in the framework of a meeting which was not open to the public, are to be considered as “*internal documents*” within the meaning of Article 4(3) of Regulation (EC) No 1049/2001 and deserve protection on that basis. The same reasoning applies, *a fortiori*, to the positions of Member States expressed in the framework of Standing Committees’ meetings and consequently referred to in documents such as minutes of other meetings.

In fact, the Member States and the Commission must be free to explore all possible options in preparation of a decision within Standing Committees free from external pressure. Public disclosure of the references to individual Member States would prevent Member States from frankly expressing their views in the framework of Standing Committees meetings and thus seriously undermining the possibility of the Commission to explore all possible options in preparation of a decision and impairing the quality of the decision-making process.

We have considered whether partial access can be granted to the documents but the exception laid down in Article 4(3), first paragraph, of Regulation (EC) No 1049/2001 applies to the documents in their entirety.

4. Overriding public interest

The exceptions to the right of access provided for in Article 4(3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested documents. In your application, you did not submit any grounds concerning a public interest on the basis of which the interests protected in Regulation (EC) No 1049/2001 would have to be overridden, and we could not identify any such ground either. In these circumstances, we have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001. The public interest in this case is rather to protect the Commission’s decision-making process.

5. Means of redress

In accordance with Article 7(2) of Regulation (EC) No 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at the following address:

European Commission
Secretary-General
Transparency unit SG-B-4
BERL 5/282
B-1049 Bruxelles
or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,



Xavier Prats Monné

⁷ Judgment of the General Court of 7 June 2013 in case T-93/11, *Stichting Corporate Europe Observatory v European Commission*, paras 32-33.

Title	Release	Reason(*): No/Partial
01. Invitation to the Workshop on EFSA Guidance Document on bees on 11-12 Dec 2013_11 Nov 2013_Ares(2013)3465067	Partial	Article 4(1)b - protection of personal data
02. Agenda Workshop on EFSA Guidance Document on bees on 11-12 Dec 2013_21 Nov 2013	Partial	Article 4(1)b - protection of personal data
03. Summary report from Workshop on EFSA Guidance Document on bees on 11-12 Dec 2013_18 Mar 2014	No	Article 4(3) first paragraph - ongoing decision making
04. Comments on Bee Guidance from Greece_19 Sep 2013	No	Article 4(3) first paragraph - ongoing decision making
05. Comments on Bee Guidance from Hungary_19 Sep 2013	No	Article 4(3) first paragraph - ongoing decision making
06. Comments on Bee Guidance from Slovakia_19 Sep 2013	No	Article 4(3) first paragraph - ongoing decision making
07. Comments on Bee Guidance from Netherlands_20 Sep 2013	No	Article 4(3) first paragraph - ongoing decision making
08. Comments on Bee Guidance from Italy_20 Sep 2013	No	Article 4(3) first paragraph - ongoing decision making
09. Comments on Bee Guidance from Spain_20 Sep 2013	No	Article 4(3) first paragraph - ongoing decision making
10. Comments on Bee Guidance from Latvia_20 Sep 2013	No	Article 4(3) first paragraph - ongoing decision making
11. Comments on Bee Guidance from Finland_1 Oct 2013	No	Article 4(3) first paragraph - ongoing decision making
12. Comments on Bee Guidance from Ireland_1 Oct 2013	No	Article 4(3) first paragraph - ongoing decision making
13. Comments on Bee Guidance from United Kingdom_5 Dec 2013	No	Article 4(3) first paragraph - ongoing decision making
14. Comments on Bee Guidance from Denmark_10 Jun 2014	No	Article 4(3) first paragraph - ongoing decision making
15. Comments on Bee Guidance from Portugal_5 Jun 2014	No	Article 4(3) first paragraph - ongoing decision making
16. Comments on Bee Guidance from Hungary_10 Jun 2014	No	Article 4(3) first paragraph - ongoing decision making
17. Comments on Bee Guidance from Italy_2 Jun 2014	No	Article 4(3) first paragraph - ongoing decision making
18. Comments on Bee Guidance from Hungary_17 May 2016	No	Article 4(3) first paragraph - ongoing decision making
19. Comments on Bee Guidance from United Kingdom_1 Jun 2016	No	Article 4(3) first paragraph - ongoing decision making
20. Comments on Bee Guidance from Hungary_9 Jun 2016	No	Article 4(3) first paragraph - ongoing decision making
21. Comments on Bee Guidance from France_10 Jun 2016	No	Article 4(3) first paragraph - ongoing decision making
22. Comments on Bee Guidance from Netherlands_10 Jun 2016	No	Article 4(3) first paragraph - ongoing decision making
23. Comments on Bee Guidance from Czech Republic_13 Jun 2016	No	Article 4(3) first paragraph - ongoing decision making
24. Comments on Bee Guidance from Italy_14 Jun 2016	No	Article 4(3) first paragraph - ongoing decision making
25. Comments on Bee Guidance from Sweden_30 Jun 2016	No	Article 4(3) first paragraph - ongoing decision making
26. Comments on Bee Guidance from Denmark_1 Jul 2016	No	Article 4(3) first paragraph - ongoing decision making
27. Comments on Bee Guidance from Netherlands_13 Jan 2017	No	Article 4(3) first paragraph - ongoing decision making
28. Comments on Bee Guidance from United Kingdom_19 Apr 2017	No	Article 4(3) first paragraph - ongoing decision making
29. Comments on Bee Guidance from Denmark_11 May 2017	No	Article 4(3) first paragraph - ongoing decision making

(*) Indicates applicable exception in Article 4 of Regulation (EC) No 1049/2001

LET/17/EJ/27490
10 March 2017

To: **Members of SCoPAFF-
phytopharmaceuticals**

Euros Jones
Director Regulatory Affairs
(+32) 2 663 15 53
euros.jones@ecpa.eu

ECPA input for SCoPAFF meeting on 22-23 March:

- **Bee Guidance document**
- **Residue definition guidance document**
- **Review of Genotoxicity evaluation**
- **PBT evaluation**
- **Co-formulants**

Dear SCoPAFF members

Ahead of the SCoPAFF-phytopharmaceutical of 22-23 March, ECPA would like to take this opportunity to provide our input on a number of generic issues. Reference is made to the meeting agenda item where relevant:

Bee guidance document (Agenda items A.16)

ECPA is supportive of a revision of the pollinator risk assessment. However, we still fail to see how the EFSA document on the risk assessment to honeybees, bumble bees and non-*Apis* bees (2013) will ensure appropriate risk assessment for pollinators and allow risk managers to take robust decisions.

In its current form the document is generating a number of uncertainties and data gaps in the conclusions of risk assessments, as observed in nearly all EFSA conclusions published since January 2016. In addition, this document elaborated between 2011 and 2013 does not rely anymore on the best scientific knowledge. We believe a new way forward is needed.

Since 2013, industry has been active in developing additional research to propose a protective and realistic way forward. Built on an analysis of the proposals included in the EFSA document, several technical suggestions and possible options have been explored for this to become a workable risk assessment process, which are compiled in the presentation enclosed with this letter. More specifically the presentation includes:

- The learning from several years of laboratory testing on honeybees
- The outcome of collaboration with expert groups during workshops, as well as up to date experience in method development.
- Further work on exposure routes
- Possible options to support chronic risk assessment of honeybee and larvae risk assessment.
- Suggestions of refinement options in higher tiers based on available new data and recent modelling developments.

ECPA will continue to ask that the Commission, EFSA and Member States:

- **Not to adopt the guidance document as it currently stands**, on the basis that it is not fit for purpose and does not provide useful support to decision making, and **reject any proposed legislative changes** when the proposed trigger values remain questionable and are not based on the most recent scientific knowledge
- **Review the progress gained in science and knowledge** over the last 3 years, before implementing the measures currently under discussion, which lead to unfeasible additional data requests.

We would welcome the opportunity to engage in a technical discussion with risk assessors and risk managers to discuss some of our suggestions and present available new data. We strongly believe that practical solutions could be jointly explored in a technical discussion with Member States and EFSA.

Further information in the Zip file enclosed – ECPA - New Industry Research and Approaches to improve the risk assessment on bees (doc.no.27576)

Residue definition guidance document

The recently published EFSA guidance document for establishing the Residue Definition for Dietary Risk Assessment will increase complexity of the evaluation process for deriving a residue definition. **A critical review of the guidance document is required before it is considered for adoption by the SCoPAFF, to ensure that the document is fit for purpose to support the regulatory process and risk manager decision-making.**

The scheme leads to an inconsistency with other national and international systems, therefore impacting global harmonisation of residue definitions and respective MRLs, import tolerances and trade. The establishment of such complex residue definitions will lead to low acceptance of Codex MRLs in Europe due to the differing residue definitions.

There are a number of areas where specific tools are required to support the implementation of the guidance document. It is essential that these essential tools and the necessary training are put in place before the adoption and application of the guidance document.

Given the significant refinements proposed in the guidance document, a testing phase is also required to understand the requirements and their very broad implications, and what ultimately it means in practice. ECPA has initiated a substance specific review and we will share the results of that review to support a better understanding of the implications of any change in the guidance.

Review of Genotoxicity evaluation

ECPA welcomes the publication of the recent mandate to the European Food Safety Authority (EFSA) for clarification and consideration of several aspects related to the assessment of genotoxicity. ECPA has identified that over the last several years the assessment of genotoxicity at EFSA has changed and in our view, the current EFSA approach is contrary to the standard global regulatory approach which considers that genotoxicity is a mode of action causal to carcinogenicity.

ECPA is encouraged to see the mandate to EFSA reflecting specific concerns on key issues; detailed written input has been provided by ECPA for consideration by the EFSA Scientific Committee in their review and we hope that the information provided will help support a robust evaluation of the issues raised in the Commission mandate.

Further information in the Zip file enclosed – ECPA input to EFSA on the genotox mandate (doc.no.27560)

PBT evaluation

ECPA have identified recent situations in the evaluation of active substances during the EFSA peer review process, where decisions are based on an ECHA/biocides guidance in the consideration of the persistence of an active substance. The biocides guidance document however contains provisions that conflict with those that apply for PPP evaluations (P evaluations for biocides are carried out at 12^oC and at 20^oC for PPPs.). We would take this opportunity to stress that the relevant guidance document should be the basis of PPP evaluations and we would ask DG SANTE and SCoPAFF members to ensure that this continues to be the case.

Further information included as annex to this letter

Co-formulants

ECPA wishes to highlight a potential risk of dual regulation of co-formulants used in Plant Protection Products under REACH, and the (yet to be populated) Regulation 1107/2009 (PPPR) Annex III negative list of co-formulants. The potential issue does not lie with REACH itself, but rather the proper co-ordination between different pieces of EU legislation.

REACH data generation and processes apply to all co-formulants, and ECPA considers that these should be used to populate PPPR 1107/2009 Annex III. The potential problem therefore lies with the fact that PPPR 1107/2009 Annex III fails to make proper links with the relevant REACH provisions.

ECPA has already highlighted the potential for the duplication of work in the evaluation of co-formulants. This concern has again been highlighted within the framework of the REACH REFIT Review. To ensure a streamlined process that avoids the duplication of effort, an EU impact assessment is required to ensure a full understanding of the implications.

Further information in the Zip file enclosed – ECPA questionnaire response (doc.no.27298) and position paper (doc.no.27240) for the REACH Refit Review.

We would of course welcome a more detailed discussion on these issues. If you have any questions about the ECPA views, please do not hesitate to contact me.

Yours sincerely



Euros Jones
Director, Regulatory Affairs

Note: To ensure full transparency, this letter is being published on the ECPA website and will be available at: <http://www.ecpa.eu/transparency-policy>.

APPENDIX 3

Mandatory tests

TESTED EFFECT	PROTOCOL
Acute oral toxicity for honeybees	OECD Test Guideline 213 : Honeybees, acute oral toxicity test
Acute oral toxicity for bumblebees	OECD Test Guideline 247 : Bumblebee, acute oral toxicity test (October 2017)
Acute contact toxicity for honeybees	OECD Test Guideline 214 : Honeybees, acute contact toxicity test
Acute contact toxicity for bumblebees	OECD Test Guideline 246 : Bumblebee, acute contact toxicity test (October 2017)
Chronic toxicity to honeybees	OECD Test Guideline 245 : Honeybee chronic toxicity test (10-day feeding) (October 2017)
Effect on honeybee development and other honeybee life stages (larval toxicity)	OECD Guidance Document 239 on Honey Bee Larval Toxicity Test following Repeated Exposure
Cage and tunnel tests for honeybees (if precedent tests did not demonstrate an acceptable risk)	EPP0 Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees
Field tests with honeybees	EPP0 Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees

Optional tests (as no agreed or finalized test guideline is available)*

TESTED EFFECT	PROTOCOL
Effects on honeybees larvae	Oomen PA, de Rujiter A and van der Steen J, 1992 // OECD Guidance Document 75 on the honeybee brood test under semi-field conditions
Chronic toxicity to bumblebees and solitary bees	OECD Test Guideline 245 : Honeybee chronic toxicity test (10-day feeding) (October 2017) adapted to bumblebees and solitary bees
Acute oral and contact toxicity to solitary bees	adapted OECD Test Guideline 213 : Honeybees, acute oral toxicity test adapted OECD Test Guideline 214 : Honeybees, acute contact toxicity test
Effect on bumblebee / solitary bees development and other life stages (larval toxicity)	- bumblebees : adapted OECD Guidance Document 239 on Honey Bee Larval Toxicity Test following Repeated Exposure - solitary bees : appendix Q, EFSA guidance document (Oral toxicity larvae)
Cage and tunnel tests for bumblebees and solitary bees (if precedent tests did not demonstrate an acceptable risk)	- bumblebees : Tasei et al., 1993. // adapted Number 75 guidance document on the honey bee (<i>apis mellifera</i> L.) brood test under semi-field conditions. - solitary bees : Ladurner et al., 2008.
Field tests with bumblebees and solitary bees (if precedent tests did not demonstrate an acceptable risk)	- bumblebees : appendix P, EFSA guidance document. - solitary bees : Torchio, 1973.

* Chronic studies with bumblebees and studies with solitary bees are also being developed, but are still in a more premature stage of development.

LET/18//30626
3 December 2018

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ECPA input for SCOPAFF phytopharmaceuticals-legislation meeting, 12-13 December 2018

- EFSA bee guidance document and update of Uniform Principles
- Sustainable Use Directive
- Endocrine disruptors
- Harmonised risk indicators
- REFIT evaluation of Regulations 1107/2009 & 396/2005

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 12-13 December 2018, ECPA would like to provide our input on several critical issues. Reference is made to the meeting agenda item where relevant:

[EFSA guidance document on the risk assessment of plant protection products on bees \(Agenda item A.08.1 and C.01\)](#)

ECPA is supportive of a robust pollinator risk assessment, however we would reiterate our requests for a significant revision of the proposed EFSA guidance document before any type of implementation. ECPA continues to collate information on EFSA conclusions on bees since January 2016 (see Attachment 1). This information indicates that for **nearly all substances (being conventional or natural based pesticides), data gaps are identified in the risk assessment and/or no risk assessment conclusion could be completed by EFSA.**

We believe that the elements suggested by the Commission as ready for implementation require substantial work before being applicable. This is the case for the **field-testing requirements, which are unrealistic and will lead to the rejection of all field and other higher tier studies.** Only a revision of the document would allow a review of the protocols for field and semi-field studies to take into account the latest scientific insights¹.

Since the EFSA guidance document was drafted in 2012, academia, industry and regulators have gained significant additional knowledge regarding pollinator risk assessment and we believe this should be taken into account in revising the document and preparing an up-to-date, protective, realistic and workable document.

We would therefore request the Commission and Member States to:

¹ See attachment 2 - An illustration of the size needed to conduct a study according to the EFSA guidance document Appendix O.

- Engage in an EU level discussion with risk assessors and risk managers with the aim of revising the EFSA guidance document before its implementation and adoption.
- Avoid legislative changes (adaptation of the Uniform Principles) when the proposed changes remain questionable, are not based on the most recent knowledge and lead to unfeasible additional data requests.

Sustainable Use Directive (Agenda item A.17)

In the context of this item, the demands made by the recent European Citizens Initiative on use reduction, and the proposal for vote under item C.01, ECPA would like to express its concern about the number of National Action Plans still not yet approved under the Sustainable Use Directive. We would encourage Member States who do not yet have one in place to submit one as soon as possible. There are rightly demands to ensure that crop protection products are being used in a sustainable way, having the action plans in place is critical to demonstrate that this requirement is being taken seriously by national governments.

Endocrine disruptors (ED) (Agenda item A.22)

Ahead of previous SCOPAFF meetings we have highlighted our significant concerns regarding the EFSA-ECHA guidance document for the assessment of endocrine disrupting properties. One of our key concerns has been the likely impact on the amount of additional vertebrate studies that maybe required. Based on emerging experience with the guidance, it appears these concerns are being realised. We are aware of at least one case where the available information clearly supports that the substance does not have endocrine disrupting properties. Yet in order to comply with the guidance, for purposes of data sufficiency, extensive unnecessary additional testing is being required despite the fact that in this case, a regulatory decision can clearly be made based on the data already available.

We would highlight that Commission Implementing Regulation 2018/1659² states that: *“When requesting additional information from the applicant, the Authority should consider that animal testing is to be minimised and tests on vertebrates are to be undertaken only as a last resort, in accordance with Article 62 of Regulation (EC) No 1107/2009.”* Regulation 2018/605 laying out the criteria for endocrine disrupting properties also clearly requires a weight of evidence based approach to be used considering the available data.

We therefore urge EFSA and the Member State experts to undertake regulatory evaluations against the criteria for endocrine disrupting properties in a manner as foreseen in Regulation 2018/605 and Regulation 2018/1659 including employing a weight of evidence approach and in a way which minimises the requests for unnecessary additional vertebrate studies.

REFIT evaluation of Regulations 1107/2009 & 396/2005 (Agenda item A.27)

ECPA supports the REFIT evaluation of the functioning of Regulations 1107/2009 and 396/2005, and we welcome the detailed contribution provided by the Ecorys report published in October³. ECPA welcomes the key conclusions of this comprehensive report which finds that *“the two Regulations are overall effective and relevant”* in enhancing protection of health and the environment. In developing the Commission’s own conclusions we would request that some of the aspects of the Ecorys report be clarified to ensure the current situation is accurately reflected and to help guide possible areas for improvement in implementation. In particular, we would highlight the conclusion that PPP uses are at risk due to difficulties met throughout both approval and MRL processes, which we believe can be overcome by improving the implementation of the current provisions. In due course we will provide our more detailed feedback on these aspects of the Ecorys report.

² Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605

³ Study supporting the REFIT evaluation of the EU legislation on plant protection products and residues (Regulation (EC) 1107/2009 and Regulation (EC) 396/2005).

Commission Draft Directive (EU) amending Directive 2009/128/EC to establish harmonised risk indicators (Agenda item C.01)

While we support the Commission's commitment to put harmonised risk indicators in place, we are concerned that the proposed indicators (based on sales statistics and number of products approved under Article 53 of Regulation 1107/2009) combined with arbitrary weighting factors, will not on their own provide an accurate indication of the relative risk. Additional factors, such as actual conditions of use, uptake of good agricultural practices, specific risk mitigation measures (where required) and dosages all determine likelihood of exposure, and would need to be included to provide a more accurate assessment and to indicate trends in risk reduction.

We support the use of easy-to-measure, implementation-based risk indicators, and believe that indicators with existing available data (e.g. in the area of water, residue monitoring or empty container collection rates) could already be included in the proposal. Only indicators requiring further work in collecting and establishing information collection systems should be scheduled for a second phase. We would also recommend the inclusion of a deadline for the development of the second phase indicators in the Directive.

Finally, we understand that this draft Directive is scheduled for voting at this SCOPAFF meeting. We would suggest, bearing in mind its own commitment to Better Regulation, that the Commission await the conclusion of the feedback mechanism consultation on 26 December, before proceeding to a vote.

We would welcome a more detailed discussion on these issues. If you have any questions regarding the ECPA views, please do not hesitate to contact me.

Yours sincerely



Peter Day
Director Regulatory Affairs

cc. Karin Nienstedt

Attachments:

- (1) Excel file with compilation of EFSA conclusions on bees published since 1 January 2016 and up to 11 November 2016.
- (2) ECPA infographic illustrating the unrealistic field-test requirements of the proposed EFSA guidance on the risk assessment of plant protection products on bees.

STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

Section *Phytopharmaceuticals - Plant Protection Products - Legislation*

https://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals_en

2018

12 DECEMBER 2018 - 13 DECEMBER 2018

A.08 Guidance Documents:

1. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

23 OCTOBER 2018 - 24 OCTOBER 2018

A.08 Guidance Documents:

1. General update and stakeholder consultation via Advisory Group on the Food Chain and Animal and Plant Health
2. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)
3. Draft Commission Notice – Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (SANTE/10407/2018 Rev.3) – final consultation before adoption

19 JULY 2018 - 20 JULY 2018

A.08 Guidance Documents:

1. Draft revised Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (short update)
2. Draft revised Guidance Document on Zonal Evaluation, Mutual Recognition Withdrawal and Amendment of Authorisations under Regulation (EC) No 1107/2009 (short

update)

3. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

24 MAY 2018 - 25 MAY 2018

A.08 Exchange of views on Guidance Documents:

1. Draft revised Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (short update)
2. Draft revised Guidance Document on Zonal Evaluation, Mutual Recognition Withdrawal and Amendment of Authorisations under Regulation (EC) No 1107/2009 (short update)
3. Draft Mandate for a Technical Guideline on the Structure of the Biological Assessment Dossier (to be noted)
4. Draft revised template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009 (SANCO/12544/2014 rev. 1, to be noted)
5. EFSA Guidance of Dermal Absorption (SANTE/ 10591/2018, to be noted)
6. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (short update)

2017

22 MARCH 2017 - 23 MARCH 2017

A.16 Bees:

1. AOB

23 JANUARY 2017 - 24 JANUARY 2017

A.16 Bees:

Review of Fipronil – state of play

Review of the Uniform Principles for Decision Making as laid down in Commission Regulation (EU) No 546/2011

Draft Commission Notice concerning time-frame for the use of EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees).

AOB

2016

06 DECEMBER 2016 - 07 DECEMBER 2016

A.16 Bees:

Review of Neonicotinoids – state of play and next steps (no news) Review of Fipronil – state of play and next steps Commission Communications amending Commission Communications (2013/C 95/01-95/02) as regards the effects on bees

Review of the Uniform Principles for Decision Making as laid down in Commission Regulation (EU) No 546/2011

Draft Commission Notice concerning time-frame for the use of EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees).

AOB

06 OCTOBER 2016 - 07 OCTOBER 2016

A.17 Bees:

1. Review of Neonicotinoids – state of play and next steps
2. Review of Fipronil – state of play and next steps
3. Commission Communications amending Commission Communications (2013/C 95/01-95/02) as regards the effects on bees
4. AOB

11 JULY 2016 - 12 JULY 2016

A.18 Bees:

1. Review of Neonicotinoids – state of play and next steps (no news)
2. Review of Fipronil – state of play and next steps
3. Commission Communications amending Commission Communications (2013/C 95/01-95/02) as regards the effects on bees
4. AOB

18 MAY 2016 - 19 MAY 2016

A.18 Bees:

Review of Neonicotinoids – state of play and next steps (no news)

Review of Fipronil – state of play and next steps

Follow-up of information received by an NGO as regards the emergency authorisations granted for neonicotinoids in accordance with Article 53 of Regulation (EC) No 1107/2009

Follow-up EFSA Conclusions on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam, clothianidin and imidacloprid considering all uses other than seed treatments and granules AOB

07 MARCH 2016 - 08 MARCH 2016

A.16 Bees:

1. Review of Neonicotinoids – state of play and next steps
2. Review of Fipronil – state of play and next steps
3. EFSA Guidance Document on the risk assessment of plant protection products on bees and implementation plan (SANCO/10606/2014) “state of play”
4. Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger values for bees to take into account the new scientific development.
5. AOB

28 JANUARY 2016 - 29 JANUARY 2016

A.16 Bees: Review of Neonicotinoids – state of play and next steps

- EFSA Guidance Document on the risk assessment of plant protection products on bees and implementation plan (SANCO/10606/2014) “state of play”

- Uniform principles – Amendment to the Regulation (EC) No 546/2011 as regards the trigger values for bees to take into account the new scientific development. Follow-up - EU Conference “Field

studies and Monitoring Activities carried out at National level on the effect of Pesticides on Bees and other Pollinators” (MAPoB) 9-11 September 2015, Bonn AOB

2015

10 DECEMBER 2015 - 11 DECEMBER 2015

Bees: Review of Neonicotinoids – state of play and next steps

EFSA Guidance Document on the risk assessment of plant protection products on bees and implementation plan (SANCO/10606/2014) “state of play”

Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger values for bees to take into account the new scientific development.

EFSA Conclusions on the peer review of the pesticide risk assessment for bees for the active substances clothianidin, imidacloprid and thiamethoxam considering all uses other than seed treatments and granules.

Report - EU Conference “Field studies and Monitoring Activities carried out at National level on the effect of Pesticides on Bees and other Pollinators” (MAPoB) – 9-11 September 2015, Bonn AOB

08 OCTOBER 2015 - 09 OCTOBER 2015

A.16 *Bees:*

1. Review of Neonicotinoids – state of play and next steps
2. EFSA Guidance Document on the risk assessment of plant protection products on bees –and implementation plan (doc. SANCO/10606/2014) “state of play”
3. Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger values for bees to take into account the new scientific development
4. EFSA Conclusions on the peer review of the pesticide risk assessment for bees for the active substances clothianidin, imidacloprid and thiametoxam

considering all uses other than seed treatments and granules

5. Report - EU Conference “Field studies and Monitoring Activities carried out at National level on the effect of Pesticides on Bees and other Pollinators”

(MAPoB) – 9-11 September 2015, Bonn

13 JULY 2015 - 14 JULY 2015

A.17 *Bees:*

Review of Neonicotinoids – state of play and next steps

EFSA Guidance document on the risk assessment of plant protection products on bees –and implementation plan (SANCO/10606/2014) “state of play”

Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger values for bees to take into account the new scientific development. EU Conference “Field studies and Monitoring Activities carried out at National level on the effect of Pesticides on Bees and other Pollinators” (MAPoB) – 9 11 September 2015, Germany AOB

28 MAY 2015 - 29 MAY 2015

A.18 *Bees:*

1. Review of Neonicotinoids – state of play and next steps
2. EFSA Guidance Document on the risk assessment of plant protection products on bees – and implementation plan (SANCO/10606/2014) “state of play”
3. Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger values for bees to take into account the new scientific development.
4. European Union Conference “Field studies and Monitoring Activities carried out at National level on the effect of

Pesticides on Bees and other Pollinators”

(MAPoB) – 9/11 September, Germany

5. European Academies Science Advisory Council report “Ecosystem services, agriculture and neonicotinoids”
6. World Conservation Union (IUCN) Red list of bees
7. New Scientific publication: Rundlof M. et al., Seed coating with neonicotinoid insecticide negatively affects wild bees, Nature
8. AOB

20 MARCH 2015

A.17 Bees:

1. Review of Neonicotinoids – state of play and next steps

2014

11 DECEMBER 2014 - 12 DECEMBER 2014

A.16 Bees:

1. Review of Neonicotinoids – state of play and next steps
2. EFSA Guidance Document on the risk assessment of plant protection products on bees – and implementation plan (SANCO/10606/2014) state of play
3. Uniform principles – Amendment to Regulation (EU) No 546/2011 as regards the trigger value for honeybees to align to the EFSA Guidance Document.
4. AOB

09 OCTOBER 2014 - 10 OCTOBER 2014

A.16 BEES- Review of Neonicotinoids – state of play and next steps

EFSA Guidance Document on the risk assessment of plant protection products on bees – and implementation plan (SANCO/10606/2014) - state of play

International symposium on the hazard of pesticides on bees AOB

10 JULY 2014 - 11 JULY 2014

2. EFSA Guidance Document on the risk assessment of plant protection products

on bees –and implementation plan (SANCO/10606/2014) “state of play”

3. Uniform principles – Amendment to the Regulation 546/2011 as regards the trigger values for bees to take into account the new scientific development. 4. AOB

26 JANUARY 2015 - 27 JANUARY 2015

A.16 Bees Review of Neonicotinoids – state of play and next steps

EFSA Guidance Document on the risk assessment of plant protection products on bees –and implementation plan (SANCO/10606/2014) state of play Uniform principles – Amendment to the Regulation 546/2011 as regards the trigger value for honeybees to align to the EFSA Guidance Document. AOB

A.16 Bees:

1. Review of Neonicotinoids – state of play and next steps
2. EFSA Guidance Document on the risk assessment of plant protection products on bees (revised version) (to be noted)
3. Implementation plan for the EFSA Guidance Document on the Risk Assessment of Plant Protection Product on Bees (SANCO/10606/2014) (to be noted) 4. AOB

15 MAY 2014 - 16 MAY 2014

Review of Neonicotinoids – state of play and next steps

1. Outcomes from working group Implementation plan for the EFSA Guidance Document on the Risk Assessment of Plant Protection Product on Bees
2. Implementation plan for the EFSA Guidance Document on the Risk Assessment of Plant Protection Product on Bees (Document SANCO/10606/2014)
3. Monitoring under the Regulations 485/2013 and 781/2013 – letter from Belgium

4. AOB

19 MARCH 2014 - 20 MARCH 2014

A.12 Bees:

1. Review of Neonicotinoids – state of play and next steps

2. Outcomes from workshop on the EFSA Bee Guidance document
3. Timeline for implementation EFSA Bee Guidance document
4. Working group
5. AOB

2013

13 DECEMBER 2013

A.9. Bees:

1. Review of Neonicotinoids – state of play and next steps
2. Outcome from workshop on the EFSA Bee Guidance document
3. AOB

2. Update on Bees Guidance document - state of play
3. Update on guidance document on operators, workers, residents and bystanders exposure – state of play

02 OCTOBER 2013 - 03 OCTOBER 2013

A.10. BEES

1. Review of Neonicotinoids – state of play and next steps
2. EFSA Bee Guidance document
3. OECD working group on pollinators
4. AOB

14 MARCH 2013 - 15 MARCH 2013

A.3 News from European Food Safety Authority (EFSA):

1. Planning
2. News from the Pesticide Unit
3. Protection goals for bees – questionnaire for risk managers
4. Guidance document on operators, workers, residents and bystanders exposure – state of play

15 JULY 2013 - 16 JULY 2013

A.10. BEES

1. Review of Neonicotinoids – state of play and next steps
2. EFSA Bee Guidance document
3. OECD working group on pollinators
4. AOB

31 JANUARY 2013 - 01 FEBRUARY 2013

A.10. Bees

Review of neonicotinoids – EFSA conclusions.

1. Review of fipronil – state of play.
2. EU Reference Laboratory on Bee health – Conclusions on a possible study on neonicotinoids to be included in surveillance programme.
3. Guidance document on bees risk assessment.
4. Bees monitoring according to Directive 2010/21/EU – state of play.
5. AOB.

16 MAY 2013 - 17 MAY 2013

A.3. News from European Food Safety Authority (EFSA):

Planning

1. News from the Pesticide Unit

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