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pesticide risk assessment procedures for pollinators are still not harmonised at the European Union level and follow outdated guidelines, which neither allow for an efficient evaluation of the new generation of pesticides nor comply with regulations for pesticide approval presently in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. POLLINIS and other environmental NGOs are concerned about the extent of the agrochemical industry's lobbying on SCoPAFF and/or the European Commission, which is the only likely explanation to date to why this process has been delayed for six years.

INTRODUCTION

POLLINATORS ARMAGEDDON

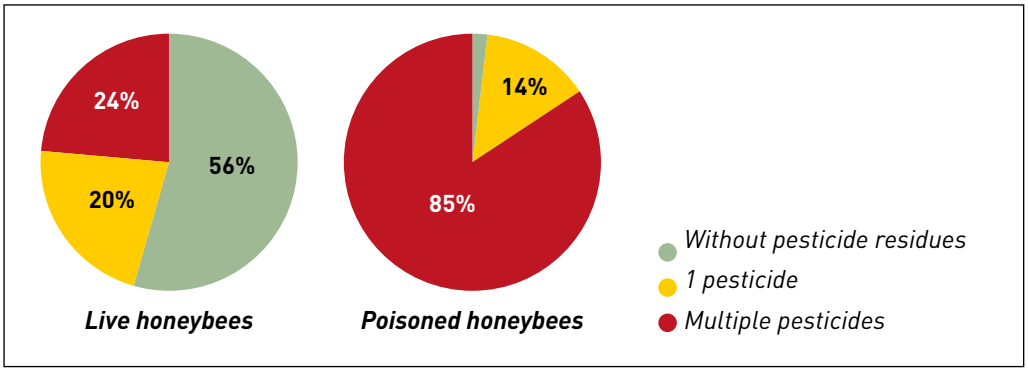
→ Testing the true impact of pesticides on bees

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 ambitous 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 chapters[3] (EPRS 2018: II-42).

Concerning pollinators (only bee species), in addition to data on acute toxicity[4], 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 guttation[5].

[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 required[6].

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 Goals[7].

→ An obsolete and inefficient risk assessment scheme

However, at the time of the promulgation of Regulations 283 and 284 (2013), the available risk assessment scheme[8], 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 ICPPR[10], an expert group whose conflicts of interest have been highlighted several times since 2007[11]. It is enough here to mention that the meetings and symposia of ICPPR are sponsored by the agrochemical industry[12], 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] Formely 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 EPPO document had close connections with the main pesticide producers or were indeed industry staff[13].

PART II

THE EFSA DOCUMENT: GOOD GUIDANCE UNDER A 6-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 States**[14].

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 confidential[15], 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 interest[16]. 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.

Being convinced that the European citizens have the right to know, POLLINIS asked the European Ombudsman to clarify:

- whether the overriding public interest is the adoption of the EFSA GD, considering the significant positive impact that it could have on the protection of pollinators and biodiversity, or the "protection of the decision making process" of the Commission;

[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).

- whether the EC has the right to refuse public disclosure of the SCoPAFF documents, which could allow citizens to scrutinise the reasons why the EFSA GD has been repeatedly not endorsed.

The Ombudsman Recommendation (see Appendix 2), issued on May, 10, 2019, states that:

" (...) the documents at issue should, in view of the context in which they were drawn-up and in view of their purpose, benefit from the wider access granted to "legislative documents" under the EU law on public access to documents. Wider access to such documents is crucial to ensure that EU citizens can exercise their treaty-based right to participate in the democratic life of the Union. The Ombudsman also considers that the documents in question contain environmental information, as defined in the Aarhus Regulation. The exception invoked by the Commission to refuse public access to the requested documents must therefore be applied all the more restrictively.

The Ombudsman also found that the Commission has not demonstrated that disclosure of the documents in question would seriously affect, prolong or complicate the proper conduct of the decision-making.

The Ombudsman therefore considers that the Commission's refusal to grant public access to the positions of Member States constituted maladministration. She recommends that the Commission should grant public access to the requested documents."

[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".

→ 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).

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 openness[17]. 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.

PART III

THE MEMBER STATES, THE COMMISSION AND THE AGROCHEMICAL LOBBY

Although the reasons why SCoPAFF refused to take note of the EFSA GD remain confidential, for the time being[18], 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 3).

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).

[18] The Ombudsman asked the EC to provide the documents required by POLLINIS by August 10, 2019 (see Appendix 2).

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 4) (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"* (see *infra* and Appendix 5). 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

Following an unfruitful attempt in 2014, the EC recently decided to relaunch the implementation plan of the EFSA GD (EC 2018) through a step wise approach, whose time-frame[19] was presented during the ad-hoc meeting of the Advisory Group on the Food Chain, Animal and Plant Health on plant protection products held in Brussels (21 September 2018).

[19] See the "Commission Notice on the time-frame for the use of the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (Apis mellifera, Bombus spp. and solitary bees)." (Appendix 7)

On this occasion, the CE representatives specified that no updating of the EFSA GD was planned for the time being: the implementation of this document would have followed its 2014 version (see Appendix 7)[20]. They also specified that:

1. the sections of the EFSA GD concerning acute and chronic toxicity for honeybees, as well as tests for larvae toxicity and exposure from different routes (surface water, puddle water, exposure to plant metabolites…), would have been immediately implemented, i.e. for all the applications submitted after June, 30, 2019;
2. other sections of the EFSA GD (accumulative risk assessment, sub-lethal effects for honeybees, risk assessment for bumblebees and solitary bees, etc.) would have been implemented at a later date, starting with the applications submitted after June, 30, 2021.

However, this proposal was rejected by SCoPAFF. Following this committee's latest meetings (October, 23-24, December, 12-13, 2018 and January, 24-25, 2019), the EC then formulated a new, "compromise" proposal, far less ambitious, whose details are known to us thanks to a leaked document (see Appendix 8).

According to this document, the EC new proposal contemplates taking the following steps:

- Adopting **only** the acute toxicity tests of the EFSA GD, limited to honeybees **only**. Considering that these tests are already systematically conducted in the current risk assessment, this represents very limited progress (the only novelty consists in the inclusion of more exposure routes in the risk assessment).
- Revising the EFSA GD before its full implementation (with a reconsideration of background mortality and trigger values).

This new proposal sounds like a requiem for bees: the impact on bumblebees and solitary bees will be ignored; the protocols on chronic and larvae toxicity will not be adopted for a long time to come, as the review process will take several years. It is difficult to understand why the EC and SCoPAFF have decided to leave out the tests on chronic and larval toxicity, when scientific evidence emphasizes that the evaluation of the lethal or sublethal effects of chronic exposure is of paramount importance to correctly assess the impact of pesticides on pollinators.

[20] "POLLINIS asked whether the 2013 document would be proposed for implementation or if it would be updated. SANTE mentioned that the 2014 document would be implemented." (Appendix 7)

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 very clear answer to this question: because most of the pesticides present on the EU market today would not pass this test (first tier).

These claims are based on an evaluation, conducted by the main pesticide producers (Bayer, BASF, Dow AgroSciences, Syngenta, FMC Agricultural Solutions, Adama), 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, emphasis added).

From the citizens' point of view, the outcomes of the industry's impact analysis clearly indicate that most of the pesticides currently on the market have a potential dangerous impact on pollinators.

However, the industry seems to be less concerned about the impact of pesticides on pollinators than about the impact of the EFSA GD on users, stakeholders and innovation. As stated in the conclusions of the impact analysis :

"The impact analysis and the follow-up work by Becker et al 2018 on larvae and with chronic adult data in this paper highlight ***the problem of releasing new guidance without proper consideration of the impact on all users and stakeholders.*** (...) ***Before implementation any new guidance with potential to impact innovation should be subject to a testing phase*** *and modified if needed to create workable processes."* (Miles *et al.* 2018: 89, emphasis added).
As we have previously seen (pp. 8-9) the *"workable processes"* evoked here are those conceived by the industry itself. On this basis, the industry has systematically opposed the adoption of the EFSA GD, claiming that this document is *"unworkable in its current form and will lead to systemic failure for almost all substances without providing workable higher tier options"* (Miles *et al.* 2018: 89). Now, it is precisely to improve *"workable higher tier options"* that the EC has proposed a step wise approach in its original proposal (July, 2018), enabling the EU to already adopt those tests that are ready for implementation, while allowing the finalisation of several higher tier options (many of which are already available).

However, more than higher tier options, what seems to be really at stake for the industry are the trigger values for chronic and larval toxicity tests established in the EFSA GD. It is important to stress that the failure rate emerging from the industry's impact analysis must be related to the trigger values (<0.03) of the chronic toxicity tests proposed by the EFSA GD, which guarantee a real protection of pollinating insects. According to ECPA, these values would be *"too conservative"*, i.e. too protective, and therefore need to be revised. In other words, from the agro-chemical industry perspective, if these tests point out the potential danger of such a high number of pesticides, their protection level needs to be lowered. The industry is therefore requesting a *"significant revision"* of the EFSA GD before any implementation.

This position is clearly stated in the ECPA *"inputs"* (i.e. pressure letters) to SCoPAFF, as can be read in the following extracts of the letters that the agrochemical association has sent to SCoPAFF following the first Commission proposal:

EXCERPT FROM A LETTER DATED 13 JULY 2018 (INTEGRAL TEXT IN APPENDIX 9):

« ECPA is supportive of a robust pollinator risk assessment, however we maintain that a significant revision of the draft EFSA guidance document is required to establish a practicable and consistent approach. (...) we have observed the practical consequences of this overly conservative document (...).
We have previously raised our concerns especially in relation to ***the conservatism of the proposed honey bee chronic trigger values*** *(which grossly overestimate the risk (...)".* (emphasis added)

EXCERPT FROM A LETTER DATED 3 DECEMBER 2018 (INTEGRAL TEXT IN APPENDIX 5):

" 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.***
(...) ***We believe that the elements suggested by the Commission as ready for implementation require substantial work before being applicable.***
We would therefore request the Commission and the Member States to:
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 (...)". (emphasis added)

Interestingly, the EC *"compromise"* proposal corresponds almost entirely to these demands of the agrochemical sector (namely, rejecting the chronic tests trigger values and requesting a *"significant revision"* of the EFSA GD before its adoption), as can be easily ascertained by comparing the above quoted ECPA's *"inputs to SCoPAFF"* and the leaked document of the Commission *"compromise"* proposal (see *infra*).

EXTRACTS FROM LEAKED DOCUMENTS SHOWING THE APPARENT CORRECTIONS MADE TO THE PLAN FOR THE ADOPTION OF THE EFSA GD BY THE EUROPEAN COMMISSION IN DECEMBER 2018 (SEE COMPLETE DOCUMENTS IN APPENDIX 8)

Part A

Parts of the EFSA guidance document to be used for applications submitted after 30 June 2019

HONEYBEES

Screening step spray applications	*Trigger value*	*Guideline/test protocol*	*Reference to the EFSA Guidance Document of 4 July 2014*
Acute contact adults	HQ > 42 (downwards spray); HQ > 85 (upwards/sideways)	OECD Test Guideline 214	Chapter 3.2.1 Table 2
Acute oral adults	ETR > 0.2	OECD Test Guideline 213	Chapter 3.2.2 Table 3
~~Chronic adults~~	~~ETR > 0.03~~	~~OECD Test Guideline 245~~	~~Chapter 3.2.2 Table 3~~
~~Larvae~~	~~ETR > 0.2~~	~~OECD Guidance Document 239~~	~~Chapter 3.2.2 Table 3~~
Exposure from surface water	ETR_{acute} adults > 0.2; ~~$ETR_{chronic}$ adults > 0.03~~ ~~$ETR_{chronic}$ larvae > 0.2~~	Use highest PEC_{sw} from FOCUS step 1 or RAC for aquatic organisms.	Chapter 3.5.2
Exposure from puddle water	ETR_{acute} adults > 0.2; ~~$ETR_{chronic}$ adults > 0.03~~ ~~$ETR_{chronic}$ larvae > 0.2~~	Use run-off PEC values from FOCUS	Chapter 34.5.3
Exposure to plant metabolites			Chapter 3.6
Screening step solid formulations	*Trigger value*	*Guideline/test protocol*	*Reference to the EFSA Guidance Document of 4 July 2014*

Part B

Parts of the EFSA guidance document to be used for applications submitted after ~~30th June 2021~~publication of the revised EFSA Guidance Document on the risk assessment for bees

As it emerges from this comparison, the modifications made to the original EC proposal pertain precisely to the chronic and larval toxicity tests, which have been deleted, together with the date originally given for the implementation of the other parts of the document, which is now replaced by the phrase *"after the publication of the revised EFSA guidance document"*. This is exactly what the agrochemical sector demanded.

EPILOGUE

THE IMBROGLIO GOES ON

Citizens and civil society associations are alarmed by the extent of the agro-chemical sector's influence on regulatory issues, and are dismayed at the umpteenth obstruction of the EFSA GD that will de facto result from the adoption of the EC "compromise" proposal.

We consider that the current EC proposal constitutes a threat for pollinators in EU, because, if endorsed by SCoPAFF, it will postpone the adoption of key tests to protect pollinators for a dangerously long time (as the review of the EFSA GD will require years to be conducted).

These concerns are shared by the European Parliament which, in a letter to the EC signed by more than 100 MEPs, has denounced such a threat (see Appendix 10).

In its response to the European Parliament (see Appendix 11), the EC (Commissioner Andriukaitis) sought to be reassuring, stating that:

"the Commission is not lowering the current level of protection with regard to chronic risks to bees. On the contrary, (...) through the implementation of the parts of the EFSA Guidance related to acute risks, including assessment of different exposure routes and new requirements for higher tier testing, that part of the risk assessment will be strengthened, while there will be no change for the chronic assessment until after the review mandated to EFSA. You will agree with me that such progress, even if limited at this moment, is preferable to continuing the 5-year imbroglio on the entire Guidance Document."

But we are concerned, as we fail to see progress[21].

Indeed, the assertion according to which *"there will be no change for the chronic assessment until after the review mandated to EFSA"*, means that, as already happens today, data on chronic toxicity may continue to be ignored in the evaluation, even if they exist[22].

We are also concerned by the announced review of the guidance document mandated to EFSA. If an updating of this document is desirable, the review should not modify the overall guidance, nor its protection goals: the EFSA GD protocols and trigger values are founded on unquestionable scientific data and have been established by the best experts in Europe throughout a in-depth and transparent scientific process. To the best of our knowledge, there is no scientific evidence indicating that these background mortality and trigger

[21] Apart from the inclusion of more exposure routes, a very minor improvement.

[22] Indeed, it is exactly what happened for the recent reevaluation of thiacloprid: chronic toxicity data were available in the dossier, but they were not taken into consideration because, according to the present evaluation scheme (EPPO 170), in case acute toxicity data do not show a major risk for bees, there is no need to consider the data on chronic toxicity in the risk assessment, even if they are available. As stated in the EFSA conclusions on thiacloprid (March 2019, p. 16): *"Acute toxicity data on honeybees were available for the active substance and the representative formulations. In addition, chronic data on adult honeybees and acute data on larvae were available. As regards the representative use on oilseed rape, the risk assessment was conducted according to the SANCO Guidance on terrestrial ecotoxicology (European Commission, 2002a), i.e. only the acute data for honeybees were taken into consideration."* In other words, this means that at present, and probably for a long time to come, robust toxicity data are, and will continue to be, ignored even if they are available. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5595

values are not correct. The only opposition to them that we were able to identify is that of the industry.

The adoption of these tests, and of the EFSA GD in general, can make a difference in the protection of pollinators in Europe. Considering the present decline rate of pollinator populations in EU, each year is crucial if we want to avoid extinction. By postponing the adoption of key tests for pollinator protection for years to come, while lowering their protection goals, we will perpetuate "the imbroglio" until pollinators disappear.

CONCLUSION

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:

1. Support the immediate implementation of the whole EFSA GD, or at least, put to the vote in the next SCoPAFF meetings the July 2018 EC proposal, i.e. including chronic toxicity and larval toxicity tests.

2. Finance and conduct research activities to accelerate the development of those test guidelines and protocols not yet available, while keeping science-based trigger values established in the EFSA GD as proposed, unless scientific data prove they are incorrect. 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.

3. 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, as recommended by the Ombudsman, that this is a matter of overriding public interest.

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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. Recommendation of the European Ombudsman in case 2142/2018/TE on the EC's refusal to grant access to MS positions on a guidance document concerning the risk assessment of pesticides on bees.
3. Letter (March 2017) from ECPA to SCoPAFF members.
4. Mandatory and optional tests of the Belgian approach (table).
5. Letter (December 2018) from ECPA to SCoPAFF members.
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APPENDIX 1
Answer from Directorate-General for Health and Food Safety to a request of documents mentioning the EFSA GD.

Ref. Ares(2018)2380851 - 04/05/2018

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@asktheeu.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 1049/2001[1].

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).

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111

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 45/2001[2].

[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 Committees[4], which the Commission adopted pursuant to Article 9 of Regulation (EC) No 182/2001[5], 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 1049/2001[6] 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.

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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* judgment[7], 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.

LIST OF DOCUMENTS RELATED TO REQUEST FOR ACCESS TO DOCUMENTS GESTDEM 2018/1680

Ref. Ares(2018)2378949 - 04/05/2018

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

European Ombudsman

Emily O'Reilly
European Ombudsman

APPENDIX 2
Recommendation of the European Ombudsman in case 2142/2018/TE on the EC's refusal to grant access to MS positions on a guidance document concerning the risk assessment of pesticides on bees.

Recommendation

of the European Ombudsman in case 2142/2018/TE on the European Commission's refusal to grant access to Member State positions on a guidance document concerning the risk assessment of pesticides on bees

Made in accordance with Article 3(6) of the Statute of the European Ombudsman[1]

Pesticides are considered to be a contributing factor in the decline of bees in Europe. Following concerns, widely raised, the European Food Safety Authority (EFSA) developed, in 2013, guidance on the assessment of risk of pesticides on bees.

The complaint, submitted by a French civil society group, concerned a request for public access to documents containing the positions of EU Member States on the 2013 EFSA guidance. The European Commission refused access on the basis that the disclosure of Member State positions would jeopardise an ongoing decision-making process.

The Ombudsman found that the documents at issue should, in view of the context in which they were drawn-up and in view of their purpose, benefit from the wider access granted to "legislative documents" under the EU law on public access to documents. Wider access to such documents is crucial to ensure that EU citizens can exercise their treaty-based right to participate in the democratic life of the Union. The Ombudsman also considers that the documents in question contain environmental information, as defined in the Aarhus Regulation. The exception invoked by the Commission to refuse public access to the requested documents must therefore be applied all the more restrictively.

The Ombudsman also found that the Commission has not demonstrated that disclosure of the documents in question would seriously affect, prolong or complicate the proper conduct of the decision-making.

The Ombudsman therefore considers that the Commission's refusal to grant public access to the positions of Member States constituted maladministration. She recommends that the Commission should grant public access to the requested documents.

[1] Decision of the European Parliament of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom), OJ 1994 L 113, p. 15.

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Background to the complaint

1. The complaint concerns the transparency of the positions of Member States in the process of adopting a guidance document on the risk assessment of pesticides on bees[2] (hereafter the 'bee guidance'). The bee guidance is intended to provide industry and authorities with guidance on how to implement EU law on the placing on the market of pesticides[3].

2. Following a request from the European Commission, the European Food Safety Authority (EFSA) issued a first version of the bee guidance in 2013, and revised it in 2014.

3. In accordance with the applicable EU law[4], guidance documents prepared by EFSA are adopted by the Commission, taking into account the advice of Member States[5]. Representatives of Member States meet and deliver their opinion on guidance documents within the scope of the Standing Committee on Plants, Animals, Food and Feed, a so-called "*comitology*"[6] committee that is chaired by the Commission.

4. Due to the absence of agreement among Member States in the Standing Committee, the adoption of the bee guidance has been delayed since 2013.

5. The complainant, the French non-profit organisation POLLINIS, asked the Commission, in March 2018, for public access to "*all correspondence (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*". Upon request, the complainant clarified the request to cover the period between July 2013 and April 2018.

6. In May 2018, the Commission responded to the complainant and identified 29 documents as falling within the scope of the request. It granted partial access to two documents and fully refused access to the remaining 27 documents on the ground that these documents contain positions of individual Member States on the draft bee guidance. The Commission argued that the public disclosure of

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[2] EFSA Guidance Document on the risk assessment of plant protection products on bees, EFSA Journal 2013;11(7):3295: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3295

[3] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1107

[4] Article 77 of Regulation 1107/2009.

[5] In accordance with the advisory procedure, as laid down in Article 4 of Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=celex:32011R0182

[6] "*Comitology*" refers to a set of procedures through which EU Member States control how the European Commission implements EU law. Before it can adopt measures which implement EU legislation, the Commission must consult, for the detailed implementing measures it proposes, a specialised committee where every EU Member State is represented. The committee in question then provides an opinion on the Commission's proposed measures. These opinions can be more or less binding on the Commission, depending on the particular procedure specified in the legal act being implemented. For a brief overview of "*comitology*", see http://ec.europa.eu/transparency/regcomitology/index.cfm?do=implementing.home

Member State positions would undermine an ongoing decision-making process[7].

7. Wishing to receive full access to all the requested documents, the complainant turned to the Ombudsman on 21 September 2018. However, since the complainant had not asked the Commission to review its decision (by making a so-called *"confirmatory application"*), the Ombudsman had to declare the complaint inadmissible at that stage.

8. In September 2018, the complainant made a new application for access to documents to the Commission, in which it repeated verbatim its request of March 2018.

9. On 13 November 2018, the Commission replied.

10. As regards the scope of the request, the Commission found that, since the complainant's previous request of March 2018 partially referred to the same documents, the new request would only cover the additional documents relating to the period between May 2018 and September 2018.

11. As regards the substance of the request, the Commission identified 16 documents as falling within its scope. As all 16 documents are email exchanges between the Commission and Member States regarding their positions on the draft bee guidance, the Commission refused access to all 16 documents with reference to the protection of an ongoing decision-making process. The Commission also argued that the complainant did not put forward any evidence of an overriding public interest in disclosure.

12. On 14 November 2018, the complainant asked the Commission to review its decision. It argued that there was an overriding public interest in disclosure, as citizens need to know why the bee guidance is repeatedly not endorsed in the Standing Committee to the detriment of the bee population.

13. On 3 December 2018, the Commission confirmed the conclusions of its initial decision.

14. Dissatisfied with the Commission's reply, the complainant turned to the Ombudsman on 12 December 2018.

The inquiry

15. The Ombudsman opened an inquiry into the complaint. The complainant's position is that the Commission:

1. wrongly limited the scope of its request to the period between May 2018 and September 2018; and

2. wrongly refused access to the requested documents.

[7] Article 4(3) of Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32001R1049

16. This recommendation addresses the second aspect of the complaint which concerns the refused access to the requested documents, showing Member State positions on the draft bee guidance. With regard to the first aspect of the complaint, the Ombudsman accepts that the Commission was legally justified[8] in refusing to deal with the part of the complainant's access request that relates to the same documents (dating from July 2013 to April 2018) to which it had previously been denied access. While she expresses her disappointment that the Commission has taken such a legalistic and citizen unfriendly approach in this case, she cannot take this matter further within the context of this inquiry.

17. The Ombudsman asked the Commission to provide full copies of the requested documents, covering the period between May 2018 and September 2018.

18. The Ombudsman furthermore invited the Commission to provide additional views on its confirmatory response to the complainant. The Commission chose not to provide any additional views.

Arguments presented by the parties

Complainant's arguments

19. The complainant considers that the 16 documents, which contain the positions of Member States on the draft bee guidance, should be disclosed in full.

20. In support of its argument, the complainant maintains that the documents in question relate to urgent measures aimed at protecting biological diversity and would therefore constitute "*environmental information*", as defined in the EU Regulation concerning public access to information in environmental matters[9] (the 'Aarhus Regulation'). The disclosure of such environmental information constitutes, according to the complainant, an overriding public interest.

21. The complainant further argues that the Commission failed to correctly balance the interests at stake. Although the Commission recognises the importance of protecting bees, it nevertheless considers that the overriding public interest lies in the protection of the decision-making process - without, however, explaining how the disclosure of the documents in question would concretely and effectively endanger that process.

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[8] The Court of Justice held in its judgment of 26 January 2010, *Internationaler Hilfsfonds v Commission*, C-362/08, para. 57, that "*a person may make a new demand for access relating to documents to which he has previously been denied access. Such an application requires the institution concerned to examine whether the earlier refusal of access remains justified in the light of a change in the legal or factual situation which has taken place in the meantime*". In the present case, it is arguable that the legal or factual situation has not changed since the Commission's first initial decision of May 2018, which became final in the absence of a confirmatory application.

[9] Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1367

Commission's arguments

22. The Commission argues that the disclosure of the 16 documents would undermine the decision-making process within the Standing Committee[10].

23. In support of its argument, the Commission notes that the decision-making process on the bee guidance is still ongoing and that Member States submitted comments in the framework of discussions within the Standing Committee on Plants, Animals, Food and Feed. The Standard Rules of Procedure for Standing Committees explicitly exclude that positions of individual Member States be disclosed[11]. The Commission further argues that, within the scope of Standing Committees, the Commission and Member States must be "*free from external pressure*" and that "[p]*ublic disclosure of the references to individual Member States would prevent Member States from frankly expressing their views*".

24. As regards the overriding public interest, the Commission acknowledges that the protection of bees is an important matter related to public health. However, it concludes that, in this particular case, "*the public interest is better served by protecting the ongoing decision-making process*". Therefore, the Commission believes there is no overriding public interest in disclosure.

The Ombudsman's assessment leading to a recommendation

25. The 16 documents in question are all emails (some of them with annexes), in which Member States respond to the Commission's invitation, expressed at the meeting of the relevant Standing Committee of 19/20 July 2018[12], to inform the Commission regarding their views on the draft bee guidance.

26. The documents contain the positions of Member State representatives on Member States' level of support and the nature of any concerns they may have regarding the content or implementation of the draft guidance.

27. The Ombudsman wishes to highlight that the 16 documents in question contain Member State positions on a draft measure whose aim it is to provide

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[10] Article 4(3) of Regulation 1049/2001.
[11] Articles 10(2) and 13(2) of the Standard Rules of Procedure for Committees - Rules of Procedure for the [Name of the committee] committee.
[12] The summary record of this meeting indicates that the bee guidance was discussed at the meeting: "*The Commission presented revision 5 of the Commission Notice regarding the implementation plan for the Bee Guidance Document. The wording of the Notice will be aligned with other Commission Notices. One Member State indicated that the EFSA Bee guidance document needs to be revised to take into account recent scientific developments. EFSA indicated that it does not consider it currently the right time to revise the Bee Guidance Document but that this can be discussed with the Commission as soon as new models become available.*
On request of a Member State, the Commission repeated its earlier explanation that a Commission Notice is not legally binding. One Member State indicated that Article 36(1) of Regulation (EC) No 1107/2009 obliges Member States to use guidance documents available at the moment of application. Member States were invited to inform the Commission regarding their support of the Commission Notice by 3 September 2018".

guidance to industry and Member States on the implementation of the EU legislation on plant protection products (pesticides). This measure is adopted via a comitology procedure, that is, the advisory procedure set out in Regulation 182/2011[13] (hereafter 'Comitology Regulation').

28. The Ombudsman further understands that, while the Commission takes the view[14] that the adopted bee guidance will not be legally binding[15], it will undoubtedly have significant practical effects on how industry will prepare, and on how Member States will examine, applications for authorisations of pesticides. This understanding is reinforced by a provision in the EU law on pesticides, which explicitly requires Member States, when examining applications for an authorisation of a pesticide, to *"make an independent, objective and transparent assessment in the light of current scientific and technical knowledge* ***using guidance documents*** *available at the time of application"*[16] (emphasis added).

29. These considerations are important, as, under the EU Treaties, every citizen has *"the right to participate in the democratic life of the Union"*[17]. Therefore, EU decisions must be taken *"as openly and as closely as possible to the citizen"*[18]. This prerogative is considered particularly important when EU institutions are acting in their *"legislative capacity"*[19]. Indeed, the possibility for citizens to scrutinise and be made aware of all the information forming the basis for EU legislative action is a precondition for the effective exercise of their democratic rights[20].

30. The EU law on public access to documents provides that not only acts adopted by the EU legislature, but also, more generally, documents drawn up or received in the course of procedures for the adoption of acts which are legally binding, must be considered *"legislative documents"* and must be made, subject to valid exceptions, directly accessible to the greatest possible extent[21]. The law specifies that *"legislative capacity"* includes the EU institutions' activity under their delegated powers[22], such as rule-making via comitology.

31. The Court of Justice has, however, in 2018, further broadened the understanding of documents that should benefit from the wider access granted

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[13] Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=celex:32011R0182. According to the advisory procedure, the Commission takes account of the opinion of the Standing Committee on Plants, Animals, Food and Feed when deciding on the adoption of a draft measure.

[14] Summary record of the meeting of the Standing Committee on Plants, Animals, Food and Feed of 19/20 July 2018.

[15] Although Article 77 of Regulation 1107/2009 provides that guidance documents are to be adopted in form of "*implementing acts*", which are legally binding.

[16] Article 36(1) of Regulation 1107/2009.

[17] Article 10 of the Treaty on European Union (TEU).

[18] Articles 1 and 10(3) TEU.

[19] Recital 6 of Regulation 1049/2001.

[20] See, to that effect, judgments of the Court of 1 July 2008, *Sweden and Turco v Council*, C-39/05 P and C-52/05 P, para. 46: http://curia.europa.eu/juris/liste.jsf?num=C-39/05&language=en, and of 17 October 2013, *Council v Access Info Europe*, C-280/11 P, para. 33: http://curia.europa.eu/juris/liste.jsf?num=C-280/11&language=EN.

[21] Article 12(2) and Recital 6 of Regulation 1049/2001.

[22] Recital 6 of Regulation 1049/2001.

to *"legislative documents"*[23]. The Court held that such wider access should also be granted to documents, in that case to impact assessments, which are not, strictly speaking, drafted by an institution when acting in its legislative capacity[24]. To come to that conclusion, the Court examined the **purpose** of impact assessments, which it considered to lie in informing the Commission's legislative proposal. The Court concluded that, as impact assessments contain *"information constituting important elements of the EU legislative process"*[25], their disclosure is *"likely to increase the transparency and openness of the legislative process as a whole"*[26]. This, the Court inferred, would *"enhance the democratic nature of the European Union by enabling its citizens to scrutinise that information and to attempt to influence that process"*[27]. Therefore, the reasons underlying the principle of a wider access to legislative documents are also valid for documents drawn up in the context of an impact assessment procedure[28].

32. The Ombudsman takes the view that an analogous assessment should be conducted for the 16 documents at issue in this case: In determining whether the documents should also benefit from the wider access attributed to *"legislative documents"*, the purpose and context of the documents in which they are drawn-up must be considered.

33. In that regard, the Ombudsman first notes that the documents in question are documents drawn up in the context of a comitology procedure. In adopting the bee guidance, the Commission acts under the powers delegated to it under the EU legislation on pesticides. In line with the EU law on public access to documents, the Commission can thus be understood to be acting in its *"legislative capacity"*.

34. Furthermore, the documents in question constitute essential information as to why a guidance document, which constitutes a measure with a significant impact on how the legislation on pesticides will be implemented in the future, has not been adopted by the Commission since 2013. In this context, the Ombudsman takes the view that the public disclosure of the 16 documents in question is likely to enhance the democratic nature of the Union by enabling its citizens, such as the complainant, to scrutinise the reasons put forward by Member States for and against the adoption of the guidance and, if wished, attempt to influence an ongoing decision-making process. The Ombudsman has consistently taken the view that understanding which positions the different representatives of Member States hold is vital in a democratic system which is accountable to its citizens.

35. In light of the above, **the Ombudsman considers that the documents in question should also benefit from the wider access granted to *"legislative documents"* under the EU law on public access to documents.**

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[23] Judgment of the Court (Grand Chamber) of 4 September 2018, *ClientEarth v Commission*, C-57/16: http://curia.europa.eu/juris/liste.jsf?num=C-57/16&language=en.
[24] Ibid, para. 86.
[25] Ibid, para. 91.
[26] Ibid, para. 92.
[27] Ibid, para. 92.
[28] Ibid, para. 95.

36. As a separate convincing reason for granting access, the Ombudsman also considers that **the documents in question contain environmental information within the meaning of the Aarhus Regulation**.

37. The Aarhus Regulation defines environmental information to include any information in written, visual, aural, electronic or any other material form on measures (including administrative measures), such as policies, legislation, plans, programmes, environmental agreements, and activities affecting or likely to affect the state of the elements of the environment, such as biological diversity and its components, as well as measures or activities designed to protect those elements[29].

38. The bee guidance outlines a process by which pesticides should be assessed, by industry and Member States when authorising such products, for their potential risk in causing harm to bees. The bee guidance is a direct response to the decline in some bee species in different regions of the world[30], which, among other factors, is caused by the release of pesticides into the environment. Against this background, the bee guidance must be understood as a measure designed to protect biological diversity.

39. In the 16 documents at issue, Member States provide their comments on that measure, including the reasons as to why Member States support its adoption or not. **The requested documents therefore contain information on a measure likely to affect biological diversity. They clearly qualify as environmental information**.

40. The Ombudsman notes that the Aarhus Regulation aims at ensuring that environmental information is progressively made available and disseminated to the public in order to achieve its widest possible systematic availability and dissemination. The purpose of access to this information is to promote more effectively public participation in the decision-making process, thereby increasing the accountability of decision-making and contributing to public awareness and support for the decisions taken[31].

41. In this spirit, the Aarhus Regulation provides that the exception in the EU law on public access to documents, which states that access to a document shall be refused if disclosure would seriously undermine the institution's decision-making process[32], **has to be interpreted in a restrictive way as regards environmental information**[33]. The public interest served by disclosure of the

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[29] Article 2(1)(d)(i) and (iii) of Regulation 1367/2006.
[30] EFSA bee guidance, p. 8.
[31] Judgment of the Court (Grand Chamber) of 4 September 2018, *ClientEarth v Commission*, C-57/16, para. 98: http://curia.europa.eu/juris/liste.jsf?num=C-57/16&language=en.
[32] Article 4(3) of Regulation 1049/2001.
[33] Article 6(1) second sentence of Regulation 1367/2006; see also Judgment of the Court (Grand Chamber) of 4 September 2018, *ClientEarth v Commission*, C-57/16, para. 100: http://curia.europa.eu/juris/liste.jsf?num=C-57/16&language=en.

requested information should be taken into account[34], thereby aiming for greater transparency of environmental information.

Application of the exception in the EU law on public access to documents

42. As the requested documents should benefit from the wider public access granted to "*legislative documents*" and, moreover, are environmental information, the Ombudsman notes that **the exception invoked by the Commission to refuse public access to the positions of Member States' representatives must be applied all the more restrictively[35]**.

43. The Commission claims that public release of the emails containing Member State positions on the bee guidance is contrary to their comitology rules of procedure (Standard Rules of Procedure for Standing Committees) which explicitly exclude the disclosure of positions of individual Member States. Furthermore, the Commission argues that the disclosure of Member State positions would significantly increase the risk of external pressure on the representatives of Member States in the Standing Committee.

44. The Ombudsman understands that the basis for the adoption of the comitology rules of procedure is Article 9 of the Comitology Regulation. However, there is no provision in the Comitology Regulation which says that summary records shall not contain the individual positions expressed by Member State representatives within the scope of committee proceedings. Nor is there any other provision in the Comitology Regulation, which would impose confidentiality requirements on committee proceedings. On the contrary, Recital 19 of that Regulation makes it clear that public access to information on committee proceedings should be ensured in accordance with the EU law on public access to documents.

45. This means that the confidentiality provisions in the comitology rules of procedure, most notably Article 10(2) (stating that summary records of meetings shall not mention the individual position of the members in the committee's discussion) and Article 13(2) (stating that the committee's discussions shall be confidential), are not themselves founded in the Comitology Regulation.

46. In light of the above, the Ombudsman takes the view that **the disclosure of Member State positions on the draft bee guidance is not contrary to the Comitology Regulation**.

47. The Ombudsman further notes that the expression by the public or interested parties of their views on the policy options envisaged, in particular in environmental matters, is an integral part of the exercise by EU citizens of their democratic rights[36].

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[34] Article 6(1) second sentence of Regulation 1367/2006; see also Judgment of the Court (Grand Chamber) of 4 September 2018, *ClientEarth v Commission*, C-57/16, para. 100: http://curia.europa.eu/juris/liste.jsf?num=C-57/16&language=en.
[35] Ibid, para. 101.
[36] Ibid, para. 101.

48. The Commission has not established that the external pressure to which Member State representatives might be subjected in the event of disclosure of the documents in question would be such as to risk impeding its capacity to act in a fully independent manner and exclusively in the general interest. The Commission has also not demonstrated that disclosure would seriously affect, prolong or complicate the proper conduct of the decision-making[37].

49. The Ombudsman therefore finds that the Commission's refusal to grant public access to the positions of Member States on the draft bee guidance constituted maladministration, in line with the considerations and principles explained above. She therefore recommends as below, in accordance with Article 3(6) of the Statute of the European Ombudsman.

Recommendation

On the basis of the inquiry into this complaint, the Ombudsman makes the following recommendation to the Commission:

The Commission should grant public access to the requested documents, showing the positions of Member States on the draft bee guidance, in line with the principles explained above.

The Commission and the complainant will be informed of this recommendation. In accordance with Article 3(6) of the Statute of the European Ombudsman, the Commission shall send a detailed opinion by **10 August 2019.**

Emily O'Reilly
European Ombudsman

Strasbourg, 10/05/2019

[37] Ibid, para. 108.

APPENDIX 3
Letter (March 2017) from ECPA to SCoPAFF members.

European Crop Protection

LET/17/EJ/27490
10 March 2017

To: Members of SCoPAFF-phytopharmaceuticals

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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.

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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^{0}C and at 20^{0}C 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.

ANNEX

PBT Assessment – Further input

PBT compounds are cut-off candidates and cannot receive (re)approval under Regulation 1107/2009. Therefore, a very diligent and prudent assessment needs to be done whether a compound meets the PBT criteria or not.

When Regulation 1107/2009 was implemented, deficiencies related to a sound classification of PBT substances were evident already. Therefore, DG SANCO released in 2012 the Working Document on "Evidence needed to identify POP, PBT and vPvB properties for pesticides", rev. 3, 25.09.2012, which has been established with the contribution of EFSA, EChA, DG Enterprise, DG Environment and several Member States (the "DG SANCO Working Document"). This document was noted in the Standing Committee. However, in recent cases EFSA did not apply the criteria set in the DG SANCO Working Document but applied a very restrictive (worst case) interpretation of the newest version of the EChA Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.11: PBT/vPVb assessment Version 2, November 2014 (the "EChA Guidance").

The EChA Guidance, however,

- is developed to assist users in complying with their obligations under Regulation (EC) No 1907/2006 (REACH regulation) and typically deals with data poor chemicals. It is not appropriate and not intended to be applied for data rich substances like plant protection products as it is based on lab data and ignores any higher tier field data;
- was passed within the framework of the REACH regime where the consequences of PBT classifications are by far less restrictive compared to the crop protection regime. Under REACH, PBT-classifications trigger a risk assessment and socio-economic assessment to identify risks and mitigation measures for the uses of the related substances, but no automatic ban;
- has neither been discussed nor noted in the Standing Committee to be applied for the PBT assessment of plant protection products

The use of the latest version of the EChA Guidance for PPP evaluations violates several Regulations of the crop protection regime, first and foremost Regulation 1107/2009, and several fundamental principles of EU law, in particular the principles of legal certainty and legitimate expectations and of scientific excellence and the rights of defence. This is mainly because the EChA Guidance is not applicable under the crop protection regime, and, even if it was deemed applicable, it would neither represent a finalized guidance as a new version is currently discussed. Therefore, crop protection industry expects that the evaluation for active substances is done strictly according to the DG SANCO Working Document released in 2012 on "Evidence needed to identify POP, PBT and vPvB properties for pesticides", rev. 3, 25.09.2012. Which is the applicable guidance for the time being.

APPENDIX 4
Mandatory and optional tests of the Belgian approach (table).

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)	EPPO Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees
Field tests with honeybees	EPPO 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	PROTOCAL
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 (apis mellifera 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.

APPENDIX 5
Letter (December 2018) from ECPA to SCoPAFF members.

European Crop Protection

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 insights[1].

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.

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- 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 2018/1659[2] 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 October[3]. 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.

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[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)

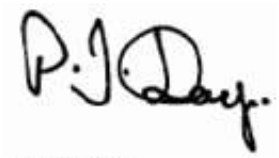
While we support the Commission's commitment to put harmonised risk indicators in place, we are concerned that the proposed indicators (based on sales statistics and number of products approved under Article 53 of Regulation 1107/2009) combined with arbitrary weighting factors, will not on their own 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.

APPENDIX 6
SCoPAFF agenda mentioning the EFSA GD (2013-2019)

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

2019

24 - 25 JANUARY 2019
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)

21 - 22 MARCH 2019
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)

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
2. Chain and Animal and Plant Health
3. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus spp.* and solitary bees)
4. 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
2. Article 43 of Regulation (EC) No 1107/2009 (short update)
3. Draft revised Guidance Document on Zonal Evaluation, Mutual Recognition Withdrawal and Amendment of Authorisations under Regulation (EC) No 1107/2009 (short update)
4. Draft Mandate for a Technical Guideline on the Structure of the Biological Assessment Dossier (to be noted)
5. 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)
6. EFSA Guidance of Dermal Absorption (SANTE/ 10591/2018, to be noted)
7. 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:

1. 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
2. Review of the Uniform Principles for Decision Making as laid down in Commission Regulation (EU) No 546/2011
3. 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).
4. 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
4. (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
4. (2013/C 95/01-95/02) as regards the effects on bees
5. AOB

18 MAY 2016 - 19 MAY 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. 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
4. 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
5. 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
5. development.
6. AOB

28 JANUARY 2016 - 29 JANUARY 2016

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 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) 9-11September 2015, Bonn

4. AOB

2015

10 DECEMBER 2015 - 11 DECEMBER 2015

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. 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.
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
6. 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:

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. 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
4. 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
4. development.
5. European Union Conference "Field studies and Monitoring Activities carried
6. out at National level on the effect of Pesticides on Bees and other Pollinators" (MAPoB) – 9/11 September, Germany

7. European Academies Science Advisory Council report "Ecosystem services, agriculture and neonicotinoids"
8. World Conservation Union (IUCN) Red list of bees

20 MARCH 2015

A.17 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 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

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 Uniform principles – Amendment to the Regulation 546/2011 as regards the trigger value for honeybees to align to the EFSA Guidance Document.
3. AOB

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 toRegulation (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

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. 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

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

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*

16 MAY 2013 - 17 MAY 2013

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

Planning

1. News from the Pesticide Unit
2. Update on Bees Guidance document - state of play
3. Update on guidance document on operators, workers, residents and

   bystanders exposure – state of play

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
5. exposure – state of play

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.

APPENDIX 7
Minutes of the ad-hoc meeting of the Advisory Group on the Food Chain, Animal and Plant Health on plant protection products, 21 September 2018, Brussels.

Minutes of the expert groups

Brussels, 26 February 2019

Minutes
ad-hoc meeting of the Advisory Group on the Food Chain, Animal and Plant Health on plant protection products
21 September 2018, CENTRE DE CONFÉRENCE ALBERT BORSCHETTES, Brussels

[...]

B - EFSA GD to be implemented (update)

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

SANTE provided an update about the status of the Commission Notice on the EFSA Bee guidance. Many comments were received with divergent opinions expressed by different stakeholders and MSs. It was agreed to take a stepwise approach and that acute and chronic risk for honey bees would be implemented in the first place.
This Commission Notice goes together with a revision of the Uniform Principles on bees. It needs to go through Inter Service Consultation in the Commission. When this will be concluded it will be taken to SCoPAFF.

ECPA asked whether it would be possible to receive the draft Commission Notice and the amendment of the Uniform Principles for consultation. SANTE explained that it has not been concluded yet if the Uniform Principles would be subject to feedback mechanism, this will be confirmed through the Inter Service Consultation.

IBMA asked for further clarification about the general and specific changes to the Uniform Principles. SANTE explained that the changes in the Uniform Principles were based on the guidance document and can be found in there.
POLLINIS asked whether the 2013 document would be proposed for implementation or if it would be updated. SANTE mentioned that the 2014 document would be implemented.

[...]

APPENDIX 8
Commission Notice of XXX [sic] Step wise implementation of the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (Apis mellifera, Bombus spp. and solitary bees).

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

EN

EN

Commission Notice of XXX

Step wise implementation of the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera, Bombus* spp. and solitary bees)

Comment [HS1]: To be moved to title page.

On 27 June 2013, the European Food Safety Authority adopted a Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera, Bombus* spp. and solitary bees)[1] and re-published on 4 July 2014 *(hereinafter, the 'EFSA Guidance Document')*. This document provides Member States (MS) and applicants with guidance on how to assess the risks to honey bees, bumble bees and solitary bees from exposure to pesticides.

In December 2013, a workshop of risk managers and risk assessors from MS concluded that the EFSA Guidance Document could not be used fully and immediately, because not all the scientific methodology was yet ready to be applicable in each area of the risk assessment. A step-wise implementation of the EFSA Guidance Document was proposed.

After further consultation with the Standing Committee on Plants, Animals, Food and Feed and aiming at a harmonised and efficient implementation, the Commission notifies that the published EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera, Bombus* spp. and solitary bees) is to be implemented as follows:

1) The chapters of the EFSA Guidance Document listed in Part A should be used for the assessment of applications for the approval or renewal of approval of active substances and for the assessment of applications for an authorisation or a renewal of authorisation of plant protection products for which a dossier is submitted after 30 June 2019 .

2) The chapters of the EFSA Guidance Document listed in Part B should be used for the assessment of applications for the approval or renewal of approval of active substances and for the assessment of applications for an authorisation or a renewal of authorisation of plant protection products for which a dossier is submitted according to the different deadlines included in the table.

3) Part C lists further actions proposed in order to allow for full implementation of the EFSA Guidance Document.

[1] European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp., doi:10.2903/j.efsa.2013.3295 Available online: www.efsa.europa.eu/efsajournal.

Field Code Changed

Part A

Parts of the EFSA guidance document to be used for applications submitted after 30 June 2019

HONEYBEES

Screening step spray applications	*Trigger value*	*Guideline/test protocol*	*Reference to the EFSA Guidance Document of 4 July 2014*
Acute contact adults	HQ > 42 (downwards spray); HQ > 85 (upwards/sideways)	OECD Test Guideline 214	Chapter 3.2.1 Table 2
Acute oral adults	ETR > 0.2	OECD Test Guideline 213	Chapter 3.2.2 Table 3
~~Chronic adults~~	~~ETR > 0.03~~	~~OECD Test Guideline 245~~	~~Chapter 3.2.2 Table 3~~
~~Larvae~~	~~ETR > 0.2~~	~~OECD Guidance Document 239~~	~~Chapter 3.2.2 Table 3~~
Exposure from surface water	ETR_{acute} adults > 0.2; ~~$ETR_{chronic}$ adults > 0.03~~ ~~$ETR_{chronic}$ larvae > 0.2~~	Use highest PEC_{sw} from FOCUS step 1 or RAC for aquatic organisms.	Chapter 3.5.2
Exposure from puddle water	ETR_{acute} adults > 0.2; ~~$ETR_{chronic}$ adults > 0.03~~ ~~$ETR_{chronic}$ larvae > 0.2~~	Use run-off PEC values from FOCUS	Chapter 34.5.3
Exposure to plant metabolites			Chapter 3.6
Screening step solid formulations	*Trigger value*	*Guideline/test protocol*	*Reference to the EFSA Guidance Document of 4 July 2014*

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Acute contact adults	HQ >14	OECD Test Guideline 214	Chapter 3.3.1 f_{dep} from Table H1b
Acute oral adults	ETR > 0.2	OECD Test Guideline 213	Chapter 3.3.2 Table 7
~~Chronic adults~~	~~ETR > 0.03~~	~~OECD Test Guideline 245~~	~~Chapter 3.3.2 Table 7~~
~~Larvae~~	~~ETR > 0.2~~	~~OECD Guidance Document 239~~	~~Chapter 3.3.2 Table 7~~
Exposure from surface water	ETR_{acute} adults > 0.2; ~~$ETR_{chronic}$ adults > 0.03~~ ~~$ETR_{chronic}$ larvae > 0.2~~	Use highest PEC_{sw} from FOCUS step 1 or RAC for aquatic organisms.	Chapter 3.5.2
Exposure from puddle water	ETR_{acute} adults > 0.2; ~~$ETR_{chronic}$ adults > 0.03~~ ~~$ETR_{chronic}$ larvae > 0.2~~	Use run-off PEC values from FOCUS	Chapter 3.5.3
Exposure to plant metabolites			Chapter 3.6
Refined risk assessment for exposure via nectar and pollen following spray applications	*Trigger value*	*Guideline/test protocol*	*Reference to the EFSA Guidance Document of 4 July 2014*
Refined exposure estimates ETR_{acute}; ~~$ETR_{chronic}$~~; ~~ETR_{larvae}~~ for all relevant scenarios	ETR_{acute} > 0.2 ~~$ETR_{chronic}$ > 0.03~~ ~~ETR_{larvae} > 0.2~~	OECD Test Guideline 213 ~~OECD Test Guideline 245~~ ~~OECD Guidance Document 239~~	Chapter 3.2.2 Ef-values from tables X1a and X2a as appropriate for the relevant scenario SV-values from Tables Jx and Jy as appropriate for the

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			relevant scenario
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 9 Appendix S
Semi-field and field effects studies		Based on EPPO 2010 and OECD 2007 with further details as provided in Appendix O	Chapter 6.1.2 and Appendix O
Refined risk assessment for contact exposure following spray application	*Trigger value*	*Guideline/test protocol*	*Reference to the EFSA Guidance Document of 4 July 2014*
Refined exposure estimate	HQ > 42 (downwards spray); HQ > 85 (upwards/sideways)	OECD Test Guideline 214	f_{dep} values from Table H1a and further guidance in Appendix H
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 9 Appendix S
Semi-field and field effects studies		EPPO 2010 and OECD 2007 with further details as provided in Appendix O especially regarding the use of statistics and the number of colonies and fields needed.	Chapter 6.1.2 and Appendix O
Refined risk assessment for exposure via nectar and pollen	*Trigger value*	*Guideline/test protocol*	*Reference to the EFSA Guidance Document of*

following seed treatment or granule application applications			*4 July 2014*
Refined exposure estimates ETR_{acute}; ~~$ETR_{chronic}$~~ ~~ETR;~~ ~~ETR_{larvae}~~ for all relevant scenarios	$ETR_{acute} > 0.2$ ~~$ETR_{chronic} > 0.03$~~ ~~$ETR_{larvae} > 0.2$~~	OECD Test Guideline 213 ~~OECD Test Guideline 245~~ ~~OECD Guidance Document 239~~	Chapter 3.3.2 SV-values from Tables Jxx and Jyy as appropriate for the relevant scenario Ef values from Table X1c
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 9 Appendix S
Semi-field and field effects studies		EPPO 2010 and OECD 2007 with further details as provided in Appendix O especially regarding the use of statistics and the number of colonies and fields needed.	Chapter 6.1.2 and Appendix O
Refined risk assessment for contact exposure following seed treatment or granule application	*Trigger value*	*Guideline/test protocol*	*Reference to the EFSA Guidance Document of 4 July 2014*
Refined exposure estimate	HQ >14	OECD Test Guideline 214	Chapter 3.3.2 Ef-values from Table X1b SV-values

			from Table Jxx
Consider risk mitigation measures Consider further refinement of exposure estimate			Chapter 9 Appendix S
Semi-field and field effects studies		EPPO 2010 and OECD 2007 with further details as provided in Appendix O especially regarding the use of statistics and the number of colonies and fields needed.	Chapter 6.1.2 and Appendix O
~~Exposure to plant metabolites~~			~~Chapter 3.6~~

Part B

Parts of the EFSA guidance document to be used for applications submitted after ~~30th June 2021~~ publication of the revised EFSA Guidance Document on the risk assessment for bees

HONEYBEES

	Guideline/test protocol	*Implementation date*	*Reference to the EFSA Guidance Document of 4 July 2014*
Chronic adults	OECD Test Guideline 245	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees	Chapter 3.2.2 Table 3 Chapter 3.3.2 Table 7 Chapter 3.5.2 Chapter 3.5.3
Larvae	OECD Guidance Document 239	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees	Ef-values from tables X1a and X2a as appropriate for the relevant scenario SV-values from Tables Jx and Jy as appropriate for the relevant scenario Ef values from Table X1c Chapter 9
Exposure from surface water	Use highest PEC_{sw} from FOCUS step 1 or RAC for aquatic organisms.	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees	
Exposure from puddle water	Use run-off PEC values from FOCUS	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees	

	Guideline/test protocol	*Implementation date*	*Reference to the EFSA Guidance Document of 4 July 2014*
			Appendix S Chapter 6.1.2 and Appendix O
Accumulative risk assessment	Research still ongoing No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 8
Repeated exposure laboratory test on larval development beyond pupation of honeybees	No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	
Screening step for assessment of exposure to residues in honeydew	No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 3 and Chapter 9
Exposure from guttation fluid	More information is needed on which crops and under what circumstances guttation droplets are produced and to what extent guttation droplets are used as a water source	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees~~30 June 2021~~	Chapter 3.5.1
Extrapolation rules for residue trials (minor crops, north-south, etc.)	[to be verified if necessary to maintain this line]	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees~~30~~	

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	Guideline/test protocol	*Implementation date*	*Reference to the EFSA Guidance Document of 4 July 2014*
		~~June 2021~~	
Sublethal effects, HPG and other methods to address physiological effects, and effects on homing flight	More information is needed No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	Appendix W
Risk from exposure to residues in succeeding crops	No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	
Development of landscape-level exposure assessment criteria/methods	No protocols yet available	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 5.1.5

BUMBLEBEES

Screening step spray applications	~~*Trigger value*~~	*Guideline/test protocol*	*Implementation date*	*Reference to the EFSA Guidance Document of 4 July 2014*~~*Reference to the restructured EFSA GD*~~

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Acute oral adults	~~ETR > 0.036 (bumble bee endpoint)~~	OECD Test Guideline 247	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees~~30 June 2021~~	Chapter 3.2.2 Table 3 8.2.1.1 Appendix P
Acute contact adults	~~HQ > 7 (downwards spray); HQ > 14 (upwards/sideways)~~	OECD Test Guideline 246	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees~~30 June 2021~~	Chapter 3.2.1 Table 2
Screening step solid formulations	~~*Trigger value*~~	*Guideline/test protocol*	*Implementation date*	*Reference to the EFSA Guidance Document of 4 July 2014~~Reference to the restructured EFSA GD~~*
Acute oral adults	~~ETR > 0.036 (based on bumble bee endpoint)~~	OECD Test Guideline 247	To be used for applications submitted after publication of the revised EFSA Guidance Document on	Chapter 3.3.2. Table 7

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			the risk assessment for bees~~30 June 2021~~	
Acute contact adults	~~HQ >2.3 (based on bumble bee endpoint)~~	OECD Test Guideline 246	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees~~30 June 2021~~	Chapter 3.3.1 f_{dep} from Table H1b
	~~Trigger value~~	*Guideline/test protocol*	*Implementation date*	*Reference to the EFSA Guidance Document of 4 July 2014*
Chronic toxicity	~~Based on honeybees end point. Reconsideration of safety factor needed.~~	No protocols yet available	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees~~30 June 2021~~	Chapter 6.2.1
Risk to larvae	~~Based on honeybees end point. Reconsideration of safety factor needed.~~	No protocols yet available	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for	Chapter 6.2.1

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			bees~~30 June 2021~~	
Higher tier studies			To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees	
Study with micro-colonies			To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees	Chapter 6.2.2 and Appendix P (with possibility for applicants to modify)
Semi-field and combined field-to-laboratory tests			To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees	Chapter 6.2.2 and Appendix P (with possibility for applicants to modify)

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SOLITARY BEES

	~~Trigger value~~	*Guideline/test protocol*	*Implementation date*	*Reference to the EFSA Guidance Document of 4 July 2014~~Reference to the restructured EFSA GD~~*
Acute contact		A ring test is currently and the test itself is ready to be implemented. However lack of guidance for higher tier testing.	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 6.3.1
Acute oral		A ring-test is currently ongoing but more work is needed regarding feeding of Osmia with a specific amount of food.	To be used for applications submitted 1 year after availability of internationally agreed protocols	Chapter 6.3.1
Chronic toxicity	~~Based on honeybees end point. Reconsideration of safety factor needed.~~	No protocols yet available.	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees~~30 June 2021~~	Chapter 6.3.1

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Risk to larvae	~~Based on honeybees end point. Reconsideration of safety factor needed~~	No protocols yet available.	To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees~~30 June 2021~~	Chapter 6.3.2.1
Semi-field and field test			To be used for applications submitted after publication of the revised EFSA Guidance Document on the risk assessment for bees ~~To be used for applications submitted 1 year after availability of internationally agreed protocols~~	Chapter 6.3.2.2 and 6.3.2.3

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Part C

Further actions proposed in order to allow for full implementation of the EFSA Guidance Document.

- A review of the Guidance Document based on new scientific information and data.
- Reconsideration of background mortality and trigger values.
- Validation (cross-check) by using available higher tier data whether the level of conservatism introduced with current trigger values seems appropriate for different toxicity tests and exposure routes.
- Detailed definition of protection goals for bumble bees and solitary bees.
- Development of the following test:
    - Chronic oral toxicity test with bumble bees.
    - Larval toxicity test with bumble bees.
    - Accumulative toxicity risk assessment for bumble bees.
    - Field tests with bumble bees.
    - Chronic oral toxicity test with solitary bees.
    - Larval toxicity test with solitary bees.
    - Accumulative toxicity risk assessment for solitary bees.

APPENDIX 9
Letter (July 2018) from ECPA to SCoPAFF members.

European Crop Protection

LET/18/PD/29957
13 July 2018

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ECPA input for SCOPAFF meeting on 19-20 July 2018:
- **EFSA bee guidance document**
- **Endocrine disruptors**
- **Amending regulation for submission of CLH dossier**
- **Harmonised risk indicators**

Dear SCOPAFF members

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 19-20 July 2018, ECPA would like to provide input on certain 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.08.3)

ECPA is supportive of a robust pollinator risk assessment, however we maintain that a significant revision of the draft EFSA guidance document is required to establish a practicable and consistent approach. Since EFSA started to use the current guidance in January 2016 to develop conclusions on active substance evaluations we have observed the practical consequences of this overly conservative document (see chart below and the enclosed Excel file compiling the EFSA bee conclusions published since 1 January 2016). The overview illustrates that for **nearly all conclusions (for conventional as well as non-conventional pesticides) data gaps are identified in the risk assessment,** a situation which does not adequately support risk management decisions.

We have previously raised our concerns especially in relation to the conservatism of the proposed honey bee chronic trigger value (which grossly overestimates risk), and to the lack of acceptable higher tier refinement options with nearly all studies submitted since 2016 being invalidated. Academia, Industry and regulators have gained significantly more knowledge on pollinator risk assessment since the EFSA document was drafted in 2012 and we believe it is now time to move forward towards a protective, realistic and applicable document taking into account these new developments

We would urge the Commission and Member States to engage in an EU level discussion with risk assessors and risk managers to explore possible ways forward, taking in to account new technical/scientific developments. We believe that practical solutions could be jointly assessed in a technical discussion with Member States and EFSA in order to develop a workable, protective and adequately calibrated risk assessment system for pollinators.

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Endocrine disruptors (ED) (Agenda item A.18.1, A.18.2, C.11)

A.18.1: We support the concept of a technical guidance document to assist the application of the ED criteria. Such guidance is essential to provide applicants and regulatory authorities with a clear framework and for ensuring consistency in the decision making process. While we acknowledge the significant amount of work undertaken by EFSA and ECHA to develop the final guidance, we still have a number of significant concerns regarding this document. Our concerns are described in more detail in the attached position paper.

We would also highlight the confusion being caused by the fact that the guidance is already being applied, but has not yet been noted in SCOPAFF. Urgent clarity is therefore required on the process and timelines for applying the guidance document against the ED criteria.

A.18.2: Following the commitment given to Member States in early 2017 to revisit the proposed amendment in points 3.6.5 and 3.8.2, Annex II, Reg 1107/2009, we are pleased that this proposal has been placed back on the SCOPAFF agenda for discussion.

In general we do not support the principle of regulation by derogation, as it does not provide the predictability needed for business to operate, and in particular for farmers to plan effectively for the future. However, given that this is the only route by which to make the ED criteria more workable, proportionate and science-based, and to avoid threatening the availability of products for farmers and the competitiveness of EU agriculture, **we support the adoption of this draft regulation, and encourage Member States to strongly support it.**

C.11: We are supportive of the proposal to prepare a regulation to amend Reg 844/2012 to allow for additional data to be submitted where considered necessary to reach regulatory decisions against the ED criteria. We would request that the regulation provide a workable and predictable procedure for managing this process and that this can be agreed and made available to applicants as soon as possible. As mentioned above, **we urgently require clarity on how the process for applying the ED criteria will be implemented in practice** leading up to and after 10 November 2018. In particular, for substances already in the renewal process, what will be the process for deciding if and what additional studies are required? We would also highlight that the complexity of any individual studies required and the global capacity of laboratories to perform these should be taken into account when setting the timeframes for the data to be submitted.

Amending Implementation Regulation (EU) No 844/2012 in view of the harmonised classification of active substances (Agenda item A.21.2)

We support the proposal to align the active substance authorisation process under Reg 1107/2009 and the harmonised classification of substances under Reg 1272/2008. We would request that progress be made urgently allowing the amending regulation to Reg 844/2012 to be agreed and adopted. ECPA member companies are willing to support Member State authorities in the process of the development and submission of CLH dossiers.

Commission Draft Directive (EU) amending Directive 2009/128/EC to establish harmonised risk indicators (Agenda item C.14)

We question whether the Commission proposal on Harmonized Risk Indicators under the Sustainable Use Directive (Dir 2009/128) as presented to Member States, will provide a reliable indication of the potential risk arising from PPP use in Europe. We support the use of easy-to-measure, implementation-based risk indicators. We believe indicators with existing available data (e.g. in the area of water or residue monitoring) should already be included in phase one of the proposal. Only indicators requiring further work in collecting and establishing information collection systems should be scheduled for a second phase.

APPENDIX 10
Letter to Commissioner Andriukaitis from Bart Staes and +100 co-signing MEPs - Implementation of EFSA Bee Guidance Document.

News

25.02.2019

Implementation of EFSA Bee Guidance Document

Letter to Commissioner Andriukaitis

Mr Vytenis Andriukaitis
Commissioner for Health and Food safety
Rue de la Loi
1049 Brussels

Cc: President of the Commission Jean-Claude Juncker
Cc :Commissioner Karmenu Vella

February 25th 2019

Implementation of EFSA Bee Guidance Document

Dear Commissioner Andriukaitis,

In May 2018, the European Commission came to an exemplary decision: to ban the outdoor use of 3 neonicotinoids (imidacloprid, clothianidin and thiamethoxam). The Commission decision was based on an in-depth assessment of these pesticides' risks to bees carried out by the European Food Safety Authority (EFSA), following the methodology described in EFSA's 2013 Bee Guidance Document.

EFSA adopted this guidance in 2013 but, despite it being considered the most comprehensive scientific reference [1] to assess the impact of pesticides on pollinators, it has still not been formally adopted by Member State governments in the Standing Committee on Plants, Animals, Food and Feed (PAFF

Committee). As a result, the guidance document is still not used consistently in the EU risk assessment of pesticides, including of other neonicotinoids[2].

However, the devastating impacts of neonicotinoids and other pesticides on pollinators and other insect species are widely documented[3][4]. Recent reports have highlighted significant declines in biodiversity with regard to birds and insects, in particular bees and other pollinators. To give an example, in the last 27 years, a decline of over 75 % in total flying insect biomass in protected areas has been observed[5].

Pollinating insects are particularly in danger, as stated in the EU Pollinators Initiative: '*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*'. This situation poses serious concerns on food security. In the 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 pollinators[6]. Biodiversity and robust ecosystems are of fundamental importance, particularly bees and other pollinating insects, to ensure a healthy and sustainable agricultural sector.

That is why the Parliament, on January 16th , with a majority of 78%, voted in favour of the Report on the Union's Pesticide authorisation procedure (the PEST report). The report reflects, inter alia, our growing concern around the issue of pesticide use and its impacts on bees and, more widely, biodiversity and the environment. In particular, the European Parliament welcomed the ban on all outdoor uses of the three neonicotinoids. Crucially it also called on the Commission and the Member States in the PAFF Committee to adopt, without delay, the updated 2013 bee guidance used by EFSA in its recent review of these three neonicotinoids.

Last year, on the 1st of March 2018, the European Parliament voted almost unanimously to support the Erdõs report on beekeeping, that called *"on the Commission and the Member States to act on the established scientific consensus and ban those pesticide active substances, including those neonicotinoids and those systemic insecticides which are scientifically proven (...) to be dangerous to bee health".*

Given the Parliament's position, we were shocked to hear that at the latest PAFF Committee meeting of 24th and 25th January 2019, the Commission proposed to EU governments to implement only a very small part of the 2013 EFSA guidance across all EU pesticide risk assessments, and to mandate EFSA to review the bulk of it. Key aspects such as chronic toxicity and risks to wild bees would be ignored until a revised guidance document is available. The apparent reason is that some governments who publicly supported the recent ban on the three neonicotinoids refuse to apply the same testing standards to other pesticides. As a result, the Commission's latest proposal eliminates requirements for the assessment of chronic toxicity and toxicity to bee larvae. It also removes deadlines for when the EU would have to assess all pesticides for potential risks to wild bees (the deadline of June 30, 2021 has been deleted for the assessment of both short- and long-term tests on honeybees, bumblebees and wild bees). Should this proposal pass, the EU would hinder rather than advance the application of EFSA's comprehensive Bee Guidance Document. It would block the application of state-of-the art bee safety standards for pesticides for years to come.

We thus urge you, both Commissioners and President of the European Commission, to do your utmost to ensure that the EFSA bee guidance is adopted in its entirety and is not weakened in any way.

Any weakening of the text will maintain existing shortcomings in the implementation of the provisions of of the EU authorisation procedure on pesticides, and thus fail to properly address the plight of Europe's bees, which are however key to the future of our biodiversity, agriculture and food security.

Given the scientific consensus on the alarming state of pollinators' health we also call you on to ensure that all pesticides, and in particular the remaining neonicotinoids, are assessed according to the same high

standards as the three neonicotinoids. Other systemic plant protection products should be restricted as much as possible, including for seed treatment, if they pose a danger to human health and the environment.

We look forward to your response on this urgent matter

Yours sincerely,

Bart STAES MEP, Co-rapporteur PEST committee

Greens/EFA
Marco AFFRONTE
Pascal DURAND
Molly SCOTT-CATO
Karima DELLI
José BOVÉ
Martin HÄUSLING
Yannick JADOT
Eva JOLY
Tilly METZ
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Jakop DALUNDE
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Miguel VIEGAS
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Joao PIMENTA LOPES

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Helga STEVENS
Peter LUNDGREN
Branislav SKRIPEK

NI
Georgios EPITIDEIOS
Udo VOIGT

[1]According to the Bee Guidance Document (BGD), new patterns of exposure (at low doses but prolonged in time) constitute an essential aspect for the evaluation of systemic pesticides. This is why the EFSA BGD considers not only a pesticide's acute toxicity to bees but introduces other important parameters to properly evaluate the risk of systemic pesticides for bees:

1. chronic toxicity arising from 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:

without these parameters in mind, the toxicity for pollinators of the three neonicotinoid recently banned (thiametoxam,clothianidine, imidacloprid) could not have been properly assessed. They need to be considered in each pesticide risk assessment in order to protect our pollinators.

[2]The assessments of the three neonicotinoids covered risks to honeybees and wild bees (bumblebees and solitary bees), including impacts from long-term exposure. EU assessments of other insecticides were either based on less stringent criteria, or only covered risks to honeybees: http://www.greenpeace.to/greenpeace/wp-content/uploads/2019/01/pesticides_beehealth.pdf

[3] http://www.eea.europa.eu/publications/late-lessons-2, see part B Section 16

[4] https://link.springer.com/article/10.1007/s11356-017-0341-3

[5] Hallmann, C.A., Sorg, M., Jongejans, E., Siepel, H., Hofland, N., Schwan, H., et al. (2017) 'More than 75 percent decline over 27 years in total flying insect biomass in protected areas'. PLoS ONE 12(10): e0185809. https://doi.org/10.1371/journal.pone.0185809

[6] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, EU Pollinators Initiative. {SWD(2018) 302 final} - {SWD(2018) 303 final}. Brussels, European Commission.

APPENDIX 11
Commissioner Andriukaitis's answer letter to Bart Staes and +100 co-signing MEPs.

Ref. Ares(2019)1902785 - 21/03/2019

European Commission

Vytenis ANDRIUKAITIS
Member of the European Commission

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21. 03. 2019

Brussels,
ARES(2019)

Mr Bart Staes, MEP (Greens)
(+ 100 co-signing MEPs)

European Parliament, Altiero Spinelli 05F258
60, rue Wiertz, B-1047 Bruxelles

Honourable Members, Dear Mr Staes,

Thank you for your letter of 25 February 2019 to President Juncker, Vice-President Katainen, Commissioner Vella, and myself, in which you raise concerns about the implementation of the EFSA Bee Guidance Document.

Let me first underline that the Commission pays the highest attention to the protection of bees, as they play an important role as pollinators not only in nature but also for many cultivated crops.

Active substances and plant protection products can only be placed on the market in the EU after a rigorous scientific assessment has shown that their use can be expected to be safe for human health and the environment, including their impacts on bees and insects. The strict actions the European Commission recently took to strengthen the protection of the environment, e.g. by banning all outdoor uses of three neonicotinoids due to concerns about their impacts on bees are at the forefront worldwide. We can all be proud of that.

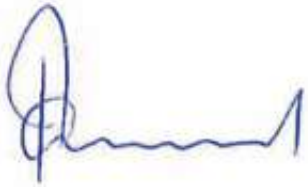
The EFSA Bee Guidance Document was adopted by EFSA in 2013 and further updated in 2014. The EFSA Bee Guidance Document has been criticised by many Member States during the discussions at the Standing Committee of Plants, Animals, Food and Feed. Attempts over the last five years to agree on the implementation of the EFSA Bee Guidance Document have failed, because many Member States do not wish to implement the Guidance before a further review, in particular for the parts related to the assessment methodology for chronic risks. The Commission is anxious to make the Guidance Notice about the implementation of the EFSA Bee Guidance Document formally applicable as soon as possible. At the same time, the Commission takes the view that guidance documents have an added value only if their content is broadly accepted by the

Member States, whose authorities are the addressees. Politically and also in view of the Member States' important role in the decision-making on active substances, the Commission prefers not to impose a document, which in practice risks being ignored or at least misapplied. Comitology is normally a collaborative process. The Commission has therefore recently proposed to make a step forward by obtaining endorsement of Member States of the parts of the Guidance Notice which are uncontested (such as the methodology related to acute risk to honeybees). In agreement with Member States, we also mandated EFSA to review its Bee Guidance Document with priority, taking into account that it is likely that new scientific evidence has become available since 2013. EFSA has also been asked to closely involve all relevant stakeholders into this process. I expect that a Guidance Notice on the implementation of the remaining parts of EFSAs reviewed Bee Guidance Document, including for chronic risk and the risk to bumble bees and solitary bees, which are the areas where most Member States wish to have a review, will then be swiftly endorsed.

I would also like to underline that the Commission is not lowering the current level of protection with regard to chronic risks to bees. On the contrary, existing data requirements on chronic risk to bees already included in Commission Regulation (EU) No 283/2013 are maintained and relevant data should be available in the application dossiers and allow assessing the potential long-term risks to bees. Furthermore, through the implementation of the parts of the EFSA Guidance related to acute risks, including assessment of different exposure routes and new requirements for higher tier testing, that part of the risk assessment will be strengthened, while there will be no change for the chronic assessment until after the review mandated to EFSA. You will agree with me that such progress, even if limited at this moment, is preferable to continuing the 5-year imbroglio on the entire Guidance Document.

Let me also emphasise that I share your concerns as regards insect and pollinator decline; indeed the situation is worrying. The causes for this decline are multifactorial and complex, and the relative importance of the factors involved are not yet established. Coordinated efforts in many areas, including on aspects of potential habitat changes for insects will be needed to stop this declining trend. That is why the Commission has initiated activities with a broader scope, such as the EU Pollinator Initiative[1].

Yours sincerely,



[1] http://ec.europa.eu/environment/nature/conservation/species/pollinators/index_en.htm

ABOUT

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