POLLINIS

ONG INDÉPENDANTE ET SANS BUT LUCRATIF QUI AGIT EXCLUSIVEMENT GRÂCE AUX DONS DES CITOYENS POUR LA PROTECTION DES ABEILLES DOMESTIQUES ET SAUVAGES, ET UNE AGRICULTURE RESPECTUEUSE DE TOUS LES POLLINISATEURS.

ÉVALUATION DES PESTICIDES ET RISQUES POUR LES POLLINISATEURS : PROCÉDURES OBSOLÈTES ET CONFLITS D'INTÉRÊTS

Comment les lignes directrices de l'EFSA sur les abeilles demeurent bloquées au niveau européen depuis six ans.

RÉSUMÉ

Face au déclin massif des pollinisateurs en Europe, l'Union européenne doit prendre des mesures urgentes. Il est d'une importance capitale de se doter d'une évaluation appropriée de l'impact des pesticides sur les espèces non ciblées. Cependant, les procédures actuelles :
- ne sont toujours pas harmonisées au niveau de l'Union européenne ;
- suivent des lignes directrices obsolètes, qui ne permettent pas une évaluation efficace des nouvelles générations de pesticides ;
- ne respectent pas la règlementation en vigueur en matière d'homologation de pesticides.

Pour se conformer au cadre règlementaire actuel, en 2013, l'Autorité européenne de sécurité des aliments (EFSA) a élaboré de nouvelles règles d'évaluation : « *Les lignes directrices sur l'évaluation des risques des produits phytopharmaceutiques pour les abeilles* (Apis mellifera, Bombus *spp. et abeilles solitaires*) », ci-après dénommé l'EFSA GD (pour *Guidance Document*). Mais depuis, son adoption au niveau européen est systématiquement bloquée par le Comité permanent des végétaux, des animaux, des denrées alimentaires et des aliments pour animaux (SCoPAFF).

Consciente de l'importance d'une évaluation adéquate des risques liés aux pesticides pour les pollinisateurs, la Commission européenne a publié un nouveau plan d'adoption de l'EFSA GD en juin 2018. Mais le SCoPAFF continue de le bloquer. L'opacité qui entoure ce comité empêche les citoyens de connaître les raisons de ce blocage et les États membres qui en sont à l'origine. En effet, tous les documents concernant le processus décisionnel du SCoPAFF sont inaccessibles, prétendument pour « *protéger le processus décisionnel* », selon la Commission. POLLINIS et les associations de la société civile s'inquiètent du poids du lobbying exercé par l'industrie agrochimique sur le SCoPAFF et/ou la Commission européenne, qui seul à ce stade pourrait expliquer le retard – six ans – pris dans ce processus.

INTRODUCTION

L'EXTINCTION DES POLLINISATEURS

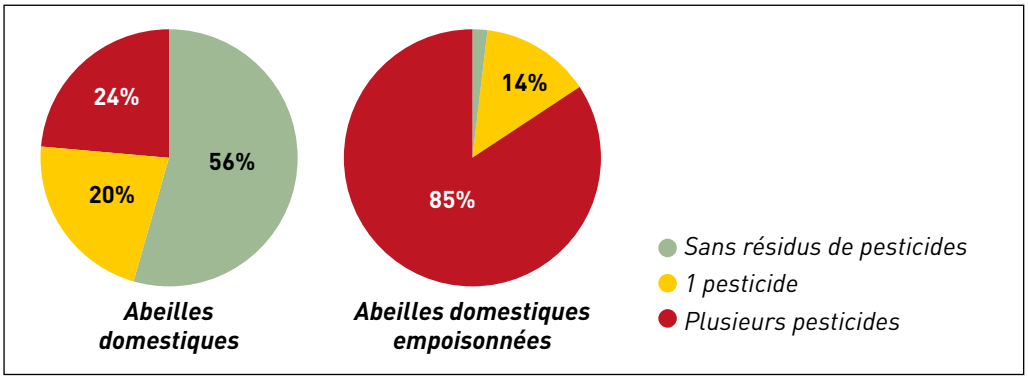
→ Tester le véritable impact des pesticides sur les abeilles

L'Europe est confrontée à un déclin massif des insectes : plus de 75 % des insectes volants ont disparu des zones protégées allemandes (Hallmann *et al.* 2017). Selon les auteurs de l'étude, ce chiffre peut être étendu à l'ensemble du territoire européen. Les insectes pollinisateurs sont particulièrement menacés : derrière le phénomène bien documenté des mortalités d'abeilles domestiques se pose un problème beaucoup plus vaste : « *le déclin spectaculaire de la fréquence et de la diversité de tous les types d'insectes pollinisateurs sauvages européens, y compris les abeilles sauvages, syrphes, papillons et papillons de nuits. De nombreuses espèces de pollinisateurs sont éteintes ou menacées d'extinction* », selon les données publiées par la Commission européenne (CE) en 2018.

Ce déclin spectaculaire aura de graves conséquences sur la sécurité alimentaire. Dans l'Union européenne (UE), environ 84 % des espèces cultivées et 78 % des espèces de fleurs sauvages dépendent, au moins en partie, de la pollinisation des animaux ; il a été évalué que la contribution des insectes pollinisateurs à la production agricole européenne s'élève à environ 15 milliards d'euros par an (CE 2018)

Le déclin des pollinisateurs est également un sujet de grave préoccupation en matière de biodiversité, car c'est l'ensemble des écosystèmes, par une réaction en chaîne, qui est touché. Comme le montrent des études récentes, le nombre d'oiseaux communs diminue à un rythme alarmant en Europe (Inger *et al.* 2014) ; en France, un tiers de la population d'oiseaux a disparu des zones rurales au cours des 15 dernières années, et ce, en raison de la disparition des insectes (MNHN 2018).

Il est donc essentiel d'adopter immédiatement des mesures pour mettre fin à ce déclin, comme l'a récemment souligné la CE dans son Initiative pour les Pollinisateurs. L'utilisation intensive de pesticides (produits phytopharmaceutiques, PPP)[1] est une des principales causes de ce déclin : en effet, l'exposition à des pesticides toxiques est une cause majeure de mortalité des pollinisateurs. L'analyse toxicologique récente d'échantillons sélectionnés d'abeilles domestiques mortes en Europe montre ainsi que 98 % des abeilles examinées étaient empoisonnées par plusieurs résidus de pesticides (Kiljanek *et al.* 2017).



PARTIE I

MISE SUR LE MARCHÉ DES PESTICIDES : AMBITION ET RÉALITÉ

→ Une réglementation européenne ambitieuse

En 2009, suite aux preuves scientifiques de plus en plus nombreuses de l'impact négatif des produits phytopharmaceutiques sur la santé humaine et l'environnement, l'UE a adopté un règlement ambitieux (n° 1107/2009)[2] visant à superviser la mise sur le marché des pesticides. Ce règlement établit comme principe fondateur la protection de la santé humaine et de l'environnement et introduit de nouveaux critères pour l'évaluation des PPP. En conséquence, dans les dossiers de demande d'homologation d'un pesticide (substance active et formulation), les études scientifiques fournies par les firmes devaient répondre à de nouvelles obligations.

[1] Le terme « pesticides » d signe les substances utilis es pour supprimer, radiquer et pr venir les organismes consid r s comme nocifs. Ils comprennent les produits biocides et les produits phytopharmaceutiques.

[2] Selon le r glement (CE) n° 1107/2009, une substance active, un phytoprotecteur ou un synergiste n'est approuv que s'il est tabli que l'utilisation des produits phytopharmaceutiques contenant cette substance active, ce phytoprotecteur ou ce synergiste entra nera une exposition n gligeable des abeilles, ou n'aura pas d'effets inacceptables aigus ou chroniques sur la survie et le d veloppement des colonies, compte tenu des effets sur les larves d'abeille et le comportement des abeilles. (Point 3.8.3, annexe II, Proc dure et crit res d'approbation des substances actives, phytoprotecteurs et synergistes conform - ment au chapitre II, R glement (CE) n° 1107/2009).

Les données requises sont détaillées dans les règlements (UE) n° 283/2013 et 284/2013, concernant respectivement l'autorisation des substances actives et des PPP, qui listent une vingtaine de nouveaux critères d'évaluation, la plupart dans les sections environnement et écotoxicologie[3] (EPRS 2018: II-42). Pour les pollinisateurs (seules les abeilles sont retenues), en plus des données sur la toxicité aiguë[4], les firmes doivent fournir des informations sur :

- la toxicité chronique pour les abeilles (abeilles mellifères, bourdons et abeilles solitaires) ;
- les effets sur le développement des abeilles mellifères et sur les autres stades de la vie des abeilles mellifères;
- le pollen et les produits des abeilles ;
- la dérive des poussières ;
- les effets sur l'eau, y compris de guttation[5].

Des données sur les effets sublétaux (tels que les effets sur le comportement ou sur la reproduction) peuvent également être requis[6].

Ces études doivent être menées en suivant des lignes directrices spécifiques, afin de permettre aux autorités compétentes de :

1. Vérifier leur exhaustivité et leur méthodologie.
2. Fournir toutes les données pertinentes pour bien évaluer le risque des pesticides et de leurs métabolites sur les abeilles.
3. Garantir le respect des objectifs de protection préalablement établis[7].

→ Un système d'évaluation des risques obsolète et inefficace

Cependant, au moment de la promulgation des règlements (UE) n° 283 et 284 (2013), le système d'évaluation des risques disponible[8] était celui défini en 2002, conformément à l'ancienne directive européenne sur les pesticides qui datait de 1991 (91/414/CEE). Ce système ne pouvait donc pas être conforme aux nouveaux critères d'approbation et aux données requises supplémentaires établis dans le nouveau cadre règlementaire, plus exigeant en matière de tests pour les abeilles. La partie concernant les abeilles, qui répertorie les essais standardisés définis par l'Organisation européenne et méditerranéenne pour la protection des plantes (OEPP)[9], a été revue en 2010 avec les recommandations de la Commission internationale pour les relations plante-pollinisateur (ICPPR), mais cette révision s'est avérée inadéquate (Simon n.d.: 9 ss.). Outre l'absence de protocoles permettant d'établir l'ensemble des nouvelles données requises, ce système d'évaluation pose problème pour plusieurs raisons :

- il est obsolète et ne peut évaluer correctement les risques posés par les nouvelles générations de pesticides comme les pesticides systémiques ;

[3] Voir European Implementation Assessment, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market.
[4] D j couverte par la pr c dente r glementation (Directive 91/4141 CEE).
[5] Voir les annexes des deux r glements : point 8.3.1 du r glement (UE) n° 283/2013 et 10.3.1 du r glement (UE) n° 284/2013, et les Communications de la Commission dans le cadre de la mise en œuvre du r glement (UE) n° 283/2013 et n°284/2013 du 1er mars 2013 tablissant les exigences en mati re de donn es applicables aux substances actives / produits phytopharmaceutiques.
[6] *« Des essais analysant les effets sublétaux, tels les effets sur le comportement et la reproduction, chez les abeilles et, le cas échéant, chez les colonies, peuvent être requis »* (r glement (UE) n° 284/2013 : point 10.3.1.4/5).
[7] Le r glement (CE) n° 1107/2009 concernant la mise sur le march des produits phytopharmaceutiques d crit bri vement les objectifs de protection au chapitre II, article 4.3 (des crit res compl mentaires applicables aux r sidus de pesticides figurent l'article 4.2). Pour une d finition d taill e des objectifs sp cifiques de protection (*« specific protection goals »*) dans le contexte de la r glementation relative aux pesticides, voir EFSA PPR 2012: 9-26.
[8] SANCO Guidance Document on Terrestrial Ecotoxicology - SANCO/10329/2002 (voir CE 2002).
[9] Chapitre 10 : les abeilles domestiques (EPPO/OEPP, 2010).

- il présente plusieurs faiblesses dans la méthodologie proposée (tests de laboratoire, semi-terrain et terrain) (EFSA PPR 2012: 48-100) ;
- il fournit uniquement des protocoles d'évaluation pour les abeilles domestiques, sans identifier les effets potentiels sur les abeilles non Apis (bourdons et abeilles solitaires) (EFSA PPR 2012: 48).

→ L'ombre des conflits d'intérêts

Depuis 2010, des eurodéputés et des associations d'apiculteurs ont manifesté leur inquiétude auprès de la Commission européenne quant à la qualité du schéma actuel d'évaluation des risques, notamment au regard des méthodes d'essais de l'OEPP (EFSA 2013: 6). En effet, ces méthodes sont fondées sur les travaux du groupe de protection des abeilles de l'ICPPR[10], un groupe d'experts dont les multiples conflits d'intérêts ont été maintes fois dénoncés depuis 2007[11]. Les réunions et colloques de l'ICPPR sont ainsi sponsorisés par l'industrie agrochimique[12], et plusieurs des experts abeilles de l'ICPPR ayant participé à la conception des tests OEPP entretiennent des liens étroits avec les principaux producteurs de pesticides, quand ils n'étaient directement employés par ces firmes[13].

PARTIE II

NOUVELLES LIGNES DIRECTRICES : UN DOCUMENT DE L'EFSA SOUMIS À SIX ANS DE BOYCOTT

Devant de telles failles, et afin de mettre en place un système d'évaluation des risques plus complet, conforme à la nouvelle réglementation, la Commission européenne a demandé à l'Autorité européenne de sécurité des aliments (EFSA) d'élaborer un nouveau cadre d'évaluation. Celle-ci a alors produit des lignes directrices sur « l'évaluation des risques liés aux produits phytopharmaceutiques pour les abeilles (*Apis mellifera, Bombus* spp. et abeilles solitaires) » - un document appelé EFSA GD (pour *Guidance Document*), qui devait apporter des instructions claires pour les demandeurs et les autorités lors de l'examen des dossiers de demande d'homologation des PPP et de leurs substances actives, conformément au règlement (CE) n° 1107/2009.

→ La méthodologie la plus adaptée à ce jour

L'EFSA a publié une première version du GD en 2013 et une version mise à jour en 2014 (EFSA 2014). Pour la première fois en Europe, l'EFSA GD fournit des directives de test appropriées et complètes pour évaluer l'impact réel des pesticides sur les abeilles (abeilles domestiques, bourdons et abeilles solitaires). Surtout, ce document se fonde sur la recherche scientifique indépendante et sur les preuves expérimentales disponibles lors de sa conception.

[10] Commission internationale pour les relations plante-pollinisateurs, anciennement Commission Internationale sur les relations plante-abeille.
[11] Pour une analyse d taill e des conflits d'int r t de l'ICPPR, voir Muilerman 2018.
[12] Par exemple, le symposium de l'ICPPR Valence en 2017 tait sponsoris par Bayer ; son 10e symposium Bucarest en 2008 tait sponsoris par 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).Voir galement Muilerman 2018.
[13] Sur les trois groupes de travail sur les abeilles, 6 experts sur 17 appartenaient au secteur industriel : 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).

L'EFSA GD propose une approche d'évaluation des risques en trois étapes, commençant par des essais en laboratoire (première étape) et, si ces derniers indiquent un risque potentiel, en procédant à des essais de semi-terrain (deuxième étape) et de terrain (troisième étape). Ces lignes directrices représentent une mise à jour du précédent modèle d'évaluation, qui ne requérait à la première étape que l'étude de la toxicité aigüe pour les abeilles domestiques, alors que l'EFSA GD exige également une analyse des risques chroniques pour les abeilles domestiques et les larves, ainsi qu'une évaluation des risques pour les bourdons (toxicité aiguë) et les abeilles solitaires.

Il convient de noter que la démarche globale de conception du GD a été pensée de manière à inclure, outre l'avis scientifique d'un groupe spécial d'experts (EFSA 2012), les résultats d'études indépendantes, en passant en revue la littérature scientifique indépendante et en organisant des consultations publiques.

Dès lors, l'EFSA GD peut être considéré à l'heure actuelle comme :

1. l'outil le plus complet, bien que non exhaustif, permettant d'évaluer les risques des PPP pour différentes espèces d'abeilles (abeilles domestiques, bourdons, abeilles solitaires) ;
2. la méthodologie la mieux adaptée disponible pour évaluer les risques posés par les pesticides systémiques ;
3. le document d'orientation le plus transparent et fondé scientifiquement.

En ce sens, l'EFSA GD représente un premier pas prometteur vers un programme complet d'évaluation des risques, tenant compte de l'impact réel des pesticides sur l'ensemble des insectes pollinisateurs, et non sur les seules abeilles.

→ Le blocage de la comitologie

Cependant, le Comité permanent des végétaux, des animaux, des denrées alimentaires et des aliments pour animaux (SCoPAFF), composé de représentants des États membres et présidé par un représentant de la Commission européenne, n'a pas encore approuvé l'EFSA GD à ce jour. Pourtant, ce même comité avait été préalablement consulté par l'EFSA pour définir les objectifs de protection à atteindre. **Cela signifie que ces nouvelles lignes directrices n'ont pas été enterinées au niveau européen et qu'il n'y a donc pas d'harmonisation des modèles d'évaluation entre les différents États membres**[14].

[14] Face un tel vide méthodologique, l'EFSA a recommandé l'approche temporaire suivante d'évaluation des risques : *«Il a été reconnu que le schéma d'évaluation du risque actuellement en vigueur à la Commission européenne (2002) n'est pas suffisant, car il ne couvre pas les nouvelles exigences en matière de données. L'EFSA a suggéré que des préoccupations particulières (fondées par exemple sur des études de cas spécifiques sur des substances actives) puissent être approfondies lors de réunions d'experts dédiées. De manière générale, en l'absence d'autres approches retenues par les gestionnaires des risques, il a été recommandé que l'évaluation des risques pour les abeilles domestiques soit réalisée (pour le premier niveau) conformément à l'EFSA (2013). Pour les études de niveau supérieur, elles doivent être évaluées de manière critique et examinées à la lumière des problèmes soulevés dans les groupes de travail de l'EFSA PPR (2012) et EFSA (2013) en ce qui concerne les méthodologies utilisées.»* (EFSA 2015: 12). Pourtant, de nombreux Etats Membres ne suivent pas ces recommandations: voir par exemple l'Allemagne (https://www.bvl.bund.de/EN/04_PlantProtectionProducts/03_Applicants/04_AuthorisationProcedure/08_Environment/ppp_bee_protection_basepage.html), qui indique toujours la méthodologie de l'OEPP.

POLLINIS ignore les raisons exactes pour lesquelles le SCoPAFF n'a pas donné son approbation : interrogée sur ce point, la Commission a répondu que, conformément au règlement (CE) n° 1049/2001, ces informations étaient confidentielles[15], afin *« de garantir la protection du processus décisionnel »* – processus décisionnel qui permettrait donc qu'aucune décision ne soit prise pendant plus de cinq ans.

Néanmoins, le règlement (CE) n° 1049/2001 précise aussi que les règles de confidentialité ne s'appliquent pas dans les affaires comportant un intérêt public supérieur[16]. À notre avis, les raisons du rejet systématique d'un modèle d'évaluation des risques qui permettrait d'empêcher les substances chimiques dangereuses pour les pollinisateurs d'arriver sur le marché, et de lutter contre la disparition des insectes en Europe, *sont* précisément des questions d'intérêt public.

Malheureusement, ce n'est pas l'avis de la direction générale de la santé et de la sécurité alimentaire (DG SANTÉ), qui a estimé que : *« il n'existe aucune preuve d'un intérêt public supérieur à la divulgation* [des documents demandés par POLLINIS]. *L'intérêt public dans cette affaire est plutôt de protéger le processus décisionnel de la Commission. »* (voir lettre en annexe 1). Apparemment, la transparence dans l'Union européenne s'arrête là où commence la comitologie. Cette situation pourrait conforter le sentiment de défiance qui croît dans la société civile européenne vis-à-vis des institutions européennes, qui semblent plus promptes à défendre les intérêts des firmes que ceux des citoyens et de l'environnement.

Convaincu que les citoyens européens ont le droit de savoir, POLLINIS a demandé à la médiatrice européenne de clarifier la situation pour déterminer :

- si l'intérêt public supérieur est l'adoption de l'EFSA GD, compte tenu de l'impact positif significatif qu'il pourrait avoir sur la protection des pollinisateurs et de la biodiversité, ou la *« protection du processus décisionnel »* ;
- si la Commission européenne a le droit de refuser l'accès du public aux documents du SCoPAFF qui pourraient permettre aux citoyens d'examiner les raisons pour lesquelles l'EFSA GD n'a pas été approuvé à de multiples reprises.

La Recommandation de la médiatrice européenne (voir annexe 2), publiée le 10 mai 2019, stipule que :
« [...] les documents en cause devraient, compte tenu du contexte dans lequel ils ont été établis et de leur objet, bénéficier de l'accès plus large accordé aux «documents législatifs» en vertu du droit communautaire sur l'accès du public aux documents. Il est essentiel d'élargir l'accès à ces documents pour garantir que les citoyens de l'UE puissent exercer leur droit garanti par les traités de participer à la vie démocratique de l'Union. La Médiatrice considère également

[15] Plus pr cis ment, sur les 29 documents recens s par la CE comme entrant dans le champ de notre demande, nous n'avons eu acc s qu' deux documents : une invitation un workshop et un formulaire de remboursement des frais de d placement du dit workshop (voir annexe 2). Les 27 autres ont t d clar s confidentiels.

[16] Il pr cise : *« L'accès à un document établi par une institution pour son usage interne ou reçu par une institution et qui a trait à une question sur laquelle celle-ci n'a pas encore pris de décision est refusé dans le cas où sa divulgation porterait gravement atteinte au processus décisionnel de cette institution, à moins qu'un intérêt public supérieur ne justifie la divulgation du document visé. »* (R glement CE n° 1049/2001, article 4, paragraphe 3, premier tiret).

que les documents en question contiennent des informations environnementales, telles que définies dans le règlement Aarhus. L'exception invoquée par la Commission pour refuser l'accès du public aux documents demandés doit donc être appliquée de manière encore plus restrictive.

La Médiatrice a également constaté que la Commission n'a pas démontré que la divulgation des documents en question affecterait, prolongerait ou compliquerait sérieusement la bonne conduite du processus décisionnel.

La Médiatrice considère donc que le refus de la Commission d'accorder l'accès du public aux positions des États membres constitue un cas de mauvaise administration. Elle recommande à la Commission d'accorder l'accès du public aux documents demandés. »

→ Quand la science rencontre la politique

On peut également se demander pourquoi des lignes directrices scientifiques sur l'évaluation des risques doivent être approuvées par le SCoPAFF, sachant que ce comité a déjà participé en amont à la définition des objectifs de protection à atteindre. Dans d'autres secteurs de la réglementation, l'EFSA est habilitée à concevoir et adopter elle-même les critères et les lignes directrices d'évaluation du risque, et leur adoption ne nécessite pas de vote politique en comitologie (EPRS 2018: II-7).

En effet, la division entre 1) l'évaluation scientifique du risque lié à l'utilisation d'un produit chimique et 2) la gestion politique de ce risque, c'est-à-dire la séparation de la phase d'évaluation de la phase de décision, est un autre principe fondateur du cadre européen d'évaluation du risque des pesticides. C'est en effet la raison d'être de l'EFSA : le règlement (CE) n° 178/2002, fondateur de l'agence, a introduit la séparation des fonctions d'évaluation du risque et de gestion de ce risque. Il a aussi entériné l'importance des valeurs fondamentales que sont l'indépendance, l'excellence scientifique, la transparence et l'objectivité[17]. Ainsi, au regard des informations fournies par l'évaluation des risques entérinée par l'agence, les gestionnaires des risques (États membres et Commission européenne réunis) décident si le composant actif d'un pesticide peut ou non être autorisé sur le marché européen.

Toutefois, lorsque l'on constate que le SCoPAFF fait obstruction à l'adoption d'un document d'orientation scientifique, on est en droit de se demander si une telle séparation fonctionnelle n'est pas mise à mal dans la pratique, avec des gestionnaires du risque qui empêchent l'adoption d'une méthode scientifique d'évaluation des risques.

[17] Le r glement non ant les principes r gissant la cr ation de l'EFSA (178/2002, art. 6.2) d clare : *« L'évaluation des risques doit être fondée sur les preuves scientifiques disponibles et être entreprise de manière indépendante, objective et transparente »*.

PARTIE III

LES ÉTATS MEMBRES, LA COMMISSION ET LE LOBBY AGROCHIMIQUE

Si les raisons pour lesquelles le SCoPAFF a refusé d'approuver l'EFSA GD restent confidentielles, jusqu'à nouvel ordre[18], nous savons que l'Association européenne de protection des cultures (ECPA), qui représente l'industrie agrochimique en Europe, s'oppose fermement à l'adoption de ce document. L'ECPA essaie constamment d'influencer le SCoPAFF pour qu'il rejette l'adoption de l'EFSA GD. L'une des lettres adressées par cette association aux membres du comité indique : *« L'ECPA continuera de demander à la Commission, à l'EFSA et aux États membres de ne pas adopter les lignes directrices en l'état actuel, car elles ne sont pas adaptées et ne fournissent pas un soutien utile à la décision »* (voir annexe 3).

Au contraire, les données requises par le GD servent bien son objectif d'évaluation de l'impact réel des pesticides sur les abeilles et aident à la prise de décision, comme le prouvent, par exemple, les récents avis scientifiques de l'EFSA (depuis 2016), en particulier ceux évaluant l'impact de trois néonicotinoïdes (thiaméthoxame, clothianidine, imidaclopride) sur les abeilles. Ces avis se fondaient sur l'EFSA GD et ont entraîné l'interdiction de ces trois molécules en Europe (EFSA 2018).

L'industrie agrochimique a également reproché à l'EFSA GD le fait que *« de nombreuses méthodes d'essais en laboratoire requises par le document d'orientation n'étaient pas disponibles ou n'avaient pas complètement été développées à des fins réglementaires »* (ECPA 2017). C'était en partie le cas en 2013, au moment de la publication du GD. Or, plusieurs de ces méthodes d'essai ont depuis été validées au niveau international (principalement par l'OCDE) et sont désormais disponibles ou en phase finale de standardisation (« ring tests »). Dès lors, au lieu de rejeter l'EFSA GD en bloc, il suffirait de le mettre à jour avec les derniers protocoles disponibles.

C'est justement ce que les autorités belges ont décidé de faire en 2018 : pour concevoir leur procédure nationale d'évaluation du risque des pesticides sur les abeilles (voir annexe 4), elles ont adopté les lignes directrices de l'EFSA, mises à jour avec les derniers protocoles d'essais de l'OCDE (SPF 2018). En effet, il est important de préciser qu'à ce jour, l'EFSA GD doit être mis à jour et, idéalement, amélioré afin de prendre en compte d'autres sources potentielles de risque (par exemple, les mélanges de pesticides non intentionnels), ainsi que d'autres espèces de pollinisateurs.

→ L'industrie agrochimique veut imposer son propre modèle d'évaluation des risques

Apparemment, l'ECPA n'est pas intéressée par une version à jour du document de l'EFSA GD : ce que l'industrie demande aux institutions européennes et aux États membres, c'est une *« révision significative »* (voir *infra* et annexe 5). Cette

[18] La m diatrice estime que *« la Commission devrait permettre au public d'accéder aux documents demandés, qui indiquent les positions des États membres sur le projet de guide des abeilles »*, et a demand la Commission europ enne d'envoyer son avis avant le 10 ao t 2019 (annexe 2).

révision significative devrait en fait se calquer sur le schéma « d'évaluation des risques pour les abeilles » mis au point par l'industrie elle-même. En effet, depuis 2013, l'ECPA met en avant une *« proposition d'approche pratique »* (ECPA 2017) pour l'évaluation des risques concernant les pollinisateurs. Comme indiqué dans le document de présentation de ce modèle d'évaluation des risques, *« [l]es caractéristiques essentielles de cette approche sont l'accent mis sur les abeilles domestiques en tant qu'espèce représentative, la définition des ensembles de données de base, la concentration sur les principales voies d'exposition et la proposition d'hypothèses plus réalistes pour le processus d'évaluation des risques »* (ECPA 2017). Lorsque l'on examine de plus près ce que l'ECPA entend par *« hypothèses plus réalistes pour le processus d'évaluation des risques »*, on constate qu'il s'agit en fait principalement « d'objectifs de protection », de niveaux d'exposition et de valeurs limites de déclenchement (une valeur de déclenchement définit un niveau au-dessus duquel les risques pour la santé humaine ou l'environnement ne peuvent pas être écartés a priori) (Wagner 2017). L'ECPA propose ainsi une limite de tolérance de 20 % pour évaluer l'impact sur les colonies (ECPA 2017) : en d'autres termes, l'industrie considère qu'un produit pouvant tuer jusqu'à 20 % des colonies est sans danger pour les abeilles, alors que l'EFSA GD fixe cette même limite à 7 % (EFSA GD 2014: 12). L'accent mis par l'ECPA sur les abeilles domestiques en tant qu'espèce représentative est également discutable si l'on considère que *« l'effet des pesticides sur les abeilles domestiques et sauvages dépend de la sensibilité intrinsèque de chaque espèce d'abeilles, mais aussi de leur cycle de vie, de leur activité de nidification et de leur façon de s'alimenter. Les données actuelles indiquent la nécessité d'avoir (...) des procédures distinctes d'évaluation des risques des pesticides pour les abeilles non-Apis »* (Arena et Sgolastra 2014).

Outre ces considérations scientifiques et méthodologiques, qui montrent que l'approche proposée par l'ECPA ne peut garantir un niveau élevé de protection pour les abeilles et les pollinisateurs en général, il convient de souligner, d'un point de vue juridique, que fonder une évaluation des risques sur un protocole élaboré par l'industrie constitue une distorsion majeure du principe du « producteur-payeur », l'un des principes clés du système européen d'évaluation des risques. Selon ce principe, c'est au producteur de pesticides (c'est-à-dire à l'entreprise qui demande une autorisation de mise sur le marché et qui bénéficiera de sa commercialisation) d'apporter la preuve qu'un pesticide n'est pas nocif. Cela explique pourquoi l'EFSA fonde ses conclusions scientifiques principalement sur des études commanditées et, dans de nombreux cas, réalisées par l'industrie elle-même sur ses propres produits.

Bien entendu, pour servir de fondement à l'évaluation et aux processus décisionnels, ces études doivent être conduites selon des protocoles spécifiques, qui respectent les exigences en matière de données fixées par les autorités compétentes.

Mais que se passe-t-il lorsque l'industrie peut définir elle-même ses propres exigences en matière de données à fournir dans les essais ?

→ Sécurité sanitaire : est-ce aux entreprises de décider ?

Dans un tel cas de figure, l'industrie mène non seulement les études nécessaires pour évaluer le risque d'un produit phytopharmaceutique pour la santé humaine et l'environnement, mais établit également les critères selon lesquels le risque potentiel de ses produits doit être évalué. L'industrie peut dès lors exclure, par exemple, les substances qui ne ciblent pas directement les insectes (tels que les fongicides et les herbicides), ou peut affirmer qu'un produit peut être considéré comme « sans danger » pour les abeilles, même s'il tue jusqu'à 20 % de la colonie, ou encore peut décider d'ignorer les espèces non-Apis. L'industrie est donc autorisée à décider de ce qui est dangereux et de ce qui ne l'est pas, donc, in fine, elle redéfinit les objectifs mêmes de protection que notre cadre réglementaire est censé imposer. Il s'agit d'un conflit d'intérêts majeur.

Il est important de souligner que le processus d'évaluation des risques repose avant tout sur la question des données requises : si ces données ne sont pas conformes aux principes de préservation établis par la loi, même le cadre juridique le plus ambitieux au monde ne pourra garantir le respect de ces objectifs.

Par conséquent, la définition de lignes directrices spécifiques pour les méthodologies d'évaluation des risques a une valeur stratégique incommensurable : elle devrait être établie par les autorités concernées à partir de la science indépendante et non par des groupes d'intérêts privés tels que l'ECPA, qui, par définition, protègent les intérêts du secteur industriel et non ceux de l'environnement.

→ L'agenda de la Commission européenne

La Commission a décidé récemment de relancer le plan de mise en œuvre de l'EFSA GD (CE 2018) avec une adoption par étapes, dont le calendrier[19] a été présenté lors de la réunion ad hoc consacrée aux produits phytopharmaceutiques du Groupe consultatif sur la chaîne alimentaire, la santé animale et végétale, qui s'est tenue à Bruxelles le 21 septembre 2018.

À cette occasion, les représentants de la Commission européenne ont précisé qu'aucune mise à jour de l'EFSA GD n'était prévue pour le moment : la mise en œuvre de ce document devait suivre la version de 2014 (voir annexe 7)[20]. Ils ont aussi précisé que :

1. les chapitres de l'EFSA GD concernant la toxicité aiguë et chronique pour les abeilles domestiques, ainsi que les tests de toxicité larvaire et d'exposition par différentes voies (eaux de surface et flaques, exposition aux métabolites des pesticides présents dans le pollen et le nectar des plantes…), devaient être immédiatement adoptés et mis en œuvre pour tous les dossiers de demandes d'homologation soumis après le 30 juin 2019 ;

[19] Voir *« 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*) » (annexe 7).
[20] *« POLLINIS a demandé si le document de 2013 sera proposé à l'adoption ou s'il sera mis à jour. La DG SANTÉ a précisé que le document de 2014 serait appliqué. »* (annexe 7).

2. d'autres parties de l'EFSA GD (évaluation des risques cumulés, effets sublétaux pour les abeilles domestiques, évaluation des risques pour les bourdons et les abeilles solitaires, etc.) devaient être mises en œuvre pour les dossiers de demande d'homologation soumis après le 30 juin 2021.

Toutefois, cette proposition a été rejetée par le SCoPAFF. Suite aux dernières réunions de ce comité (23-24 octobre, 12-13 décembre 2018 et 24-25 janvier 2019), la Commission a formulé une nouvelle proposition de « compromis », beaucoup moins ambitieuse, dont les détails ont été révélés par un document fuité (voir annexe 8).

Selon ce document, la nouvelle proposition de la Commission envisage de prendre les mesures suivantes :

- n'adopter que les tests de **toxicité aiguë** de l'EFSA GD, et seulement pour les **abeilles domestiques**. Étant donné que ces tests sont déjà systématiquement effectués dans le cadre de l'évaluation du risque actuelle, cela représente un progrès très limité (la seule nouveauté consiste à inclure davantage de voies d'exposition dans l'évaluation) ;
- réviser l'EFSA GD avant sa complète adoption (avec un réexamen des taux de mortalité et des valeurs seuils de toxicité).

Cette nouvelle proposition ressemble à un requiem pour les abeilles : l'impact sur les bourdons et les abeilles solitaires sera ignoré; les protocoles sur la toxicité chronique et larvaire ne seront pas adoptés avant longtemps puisque le processus de révision prendra plusieurs années. Il est incompréhensible que la Commission et le SCoPAFF aient décidé de ne pas retenir les tests de toxicité chronique et larvaire, alors que les preuves scientifiques montrent l'importance d'une évaluation des effets létaux et sublétaux d'une exposition chronique pour évaluer correctement l'impact des pesticides sur les pollinisateurs.

L'IMPORTANCE DES TESTS DE TOXICITÉ CHRONIQUE

La nouvelle génération de pesticides systémiques présente plusieurs différences par rapport aux pesticides plus anciens, qui sont généralement pulvérisés en extérieur sur les plantes. Ces derniers peuvent contaminer les cultures voisines si la pulvérisation dérive avec le vent et, bien que cela puisse être particulièrement dangereux en termes de toxicité aiguë, cette toxicité disparaît généralement en quelques jours. Les pesticides systémiques, par contre, peuvent migrer vers les cultures voisines non traitées et les fleurs sauvages, loin des champs où ils sont utilisés ; ils peuvent aussi persister pendant des années dans l'environnement. La clothianidine, par exemple, a une demi-vie de 19 ans dans les sols argileux (Simon n.d.: 4).

Les modes d'exposition et les effets toxiques des pesticides systémiques diffèrent donc radicalement de ceux des pesticides utilisés en pulvérisation : pour les pesticides systémiques, l'exposition peut certes se produire à des doses plus faibles mais elle peut être prolongée dans le temps et sur des surfaces bien plus grandes. L'exposition peut même se produire au sein des ruches en raison des résidus présents dans le pollen et les différents produits apicoles. De plus, l'exposition a des impacts différents selon le stade de développement des insectes.

Ces nouveaux modes d'exposition (à faibles doses mais prolongés dans le temps) constituent un aspect essentiel de l'évaluation des pesticides systémiques : c'est pourquoi, outre la toxicité aiguë, l'EFSA GD introduit dans sa première phase de tests plusieurs paramètres importants permettant d'évaluer correctement le risque de contamination des abeilles par des pesticides systémiques :

1. la toxicité chronique pour évaluer une exposition plus longue dans le temps et ses effets d'accumulation ;
2. des routes d'exposition multiples dans l'alimentation (pollen, nectar, miellat), l'eau (eaux de guttation, eaux de surface) et l'habitat (sol, poussière, etc.) ;
3. les effets sur les différentes étapes de la vie des abeilles et les effets susceptibles d'affecter l'ensemble de la colonie (pour les abeilles domestiques).

Ces paramètres, y compris l'évaluation de la toxicité chronique, sont d'une importance capitale : aucune évaluation des risques ne peut être exacte s'ils ne sont pas pris en compte.

Par contre, lorsque ces paramètres sont pris en compte, les résultats changent : par exemple, la toxicité pour les pollinisateurs des trois molécules néonicotinoïdes (thiaméthoxame, clothianidine, imidaclopride), récemment interdites dans l'UE (sauf sous serres), a pu être détectée et mesurée grâce aux protocoles indiqués dans l'EFSA GD.

Alors, pourquoi ne pas adopter ces tests de toxicité chronique, pourtant indispensables ?

Dans son « étude d'impact » de l'EFSA GD, l'industrie agrochimique apporte une réponse assez claire à cette question : car la plupart des pesticides présents sur le marché de l'UE aujourd'hui ne passeraient pas ces tests (dès la première étape).

Cette affirmation découle d'une étude, menée par les principaux producteurs de pesticides (Bayer, BASF, Dow AgroSciences, Syngenta, FMC Agricultural

Solutions, Adama), sur le *« taux de réussite/d'échec des substances actives actuellement disponibles sur le marché de l'UE »* si elles devaient être évaluées selon l'EFSA GD (Miles *et al.* 2018: 87). Cette étude montre notamment que le taux de réussite/d'échec pour le risque aigu selon l'EFSA GD est similaire aux résultats actuels de l'évaluation des risques, mais qu'une différence significative est apparue pour les tests de toxicité chronique (Miles *et al.* 2018: 87-8). Dans ce cas, ***« 79 % de toutes les utilisations d'herbicides ont échoué, ainsi que 75 % des utilisations de fongicides et 92 % des utilisations d'insecticides. »*** (Miles *et al.* 2018: 88).

Du point de vue des citoyens, les résultats de l'analyse d'impact de l'industrie indiquent que la plupart des pesticides actuellement sur le marché ont un impact potentiellement dangereux sur les pollinisateurs.

Toutefois, l'industrie semble moins préoccupée par l'impact des pesticides sur les pollinisateurs que par l'impact de l'EFSA GD sur les parties prenantes et l'innovation en général. Comme indiqué dans les conclusions de l'analyse d'impact :

« L'analyse d'impact et le travail de suivi de Becker et al 2018 sur les larves et les données chroniques sur les adultes, dans ce document, mettent en évidence ***le problème de la publication de nouvelles lignes directrices sans considération adéquate de l'impact sur tous les utilisateurs et parties prenantes. (...) Avant leur mise en œuvre, toutes nouvelles lignes directrices susceptibles d'avoir un impact sur l'innovation devraient être soumises à une phase d'essai*** *et modifiées si nécessaire pour créer des processus viables. »* (Miles *et al.* 2018: 89) [caractère gras ajouté].

Comme nous l'avons vu précédemment (p. 9), les *« processus viables »* évoqués ici sont ceux conçus par l'industrie elle-même. Sur ce fondement, l'industrie s'est systématiquement opposée à l'adoption de l'EFSA GD, affirmant que ce document est *« inapplicable dans sa forme actuelle et qu'il entraînera un échec systémique pour presque toutes les substances, sans fournir d'options applicables pour les échelons supérieurs* [de l'évaluation] » (Miles *et al.*2018: 89). Or, c'est précisément pour améliorer les *« options des échelons supérieurs »* de l'évaluation (essais de semi-terrain et de terrain) que la Commission a proposé une adoption par étapes dans sa proposition initiale (juillet 2018), permettant à l'UE d'adopter les tests déjà prêts pour exécution, tout en permettant la finalisation de plusieurs tests de niveau supérieur (dont beaucoup sont déjà disponibles).

Toutefois, au-delà des tests de niveau supérieur, ce qui semble être réellement en jeu pour l'industrie, ce sont les valeurs seuils des essais de toxicité chronique et larvaire établies dans l'EFSA GD. Il est important de souligner que le taux d'échec issu de l'analyse d'impact de l'industrie doit être lié aux valeurs seuils (<0,03) des tests de toxicité chronique retenues par l'EFSA GD, qui garantissent une réelle protection des insectes pollinisateurs. Or, selon l'ECPA, ces valeurs seraient *« trop conservatrices »*, c'est-à-dire trop protectrices, et devraient donc être revues. En d'autres termes, du point de vue

de l'industrie agrochimique, si ces tests mettent en évidence le danger potentiel d'un nombre aussi élevé de pesticides, leur niveau de protection doit être réduit. L'industrie demande donc une *« révision significative »* de l'EFSA GD avant toute mise en œuvre.

Cette position est clairement exprimée dans les *« contributions »* (c'est-à-dire les lettres de pression du lobby agrochimique sur ce comité). de l'ECPA au SCoPAFF suite à la première proposition de la Commission :

EXTRAIT D'UNE LETTRE DU 13 JUILLET 2018 (TEXTE COMPLET EN ANNEXE 9) :

« L'ECPA est favorable à une évaluation rigoureuse des risques pour les pollinisateurs, mais nous maintenons toutefois qu'une révision importante du projet des Lignes directrices de l'EFSA est nécessaire pour établir une approche pratique et cohérente. (...) nous avons observé les conséquences pratiques de ce document trop conservateur (...).
Nous avons déjà fait part de nos préoccupations, notamment en ce qui concerne ***le conservatisme des valeurs seuils de toxicité chronique proposées pour les abeilles domestiques*** *(qui surestiment considérablement le risque (...) ».* [caractère gras ajouté]

EXTRAIT D'UNE LETTRE DU 3 DÉCEMBRE 2018 (TEXTE COMPLET EN ANNEXE 5) :

« L'ECPA est favorable à une évaluation rigoureuse des risques pour les pollinisateurs, ***mais nous réitérons notre demande d'une révision importante des lignes directrices de l'EFSA avant tout type de mise en œuvre.***
(...) Nous pensons que les éléments suggérés par la Commission comme étant prêts à être mis en œuvre nécessitent un travail considérable avant d'être applicables.
Nous demandons donc à la Commission et aux États membres :
D'engager une discussion au niveau de l'UE avec les évaluateurs et les gestionnaires de risques dans le but de réviser les lignes directrices de l'EFSA avant sa mise en œuvre et son adoption (...) ». [caractère gras ajouté]

La proposition de *« compromis »* de la Commission répond presque entièrement aux exigences du secteur agrochimique (à savoir, rejeter les valeurs seuils des essais de toxicité chronique et demander une *« révision significative »* de l'EFSA GD avant son adoption).

La comparaison des « contributions de l'ECPA au SCoPAFF » mentionnées ci-dessus et de la dernière proposition de *« compromis »* de la Commission qui a fuité (voir documents ci-après) illustrent cette main-mise de l'industrie sur le processus de négociation.

EXTRAITS DE DOCUMENTS FUITÉS MONTRANT LES CORRECTIONS APPARENTES APPORTÉES AU PLAN D'ADOPTION DE L'EFSA GD PAR LA COMMISSION EUROPÉENNE EN DÉCEMBRE 2018 (VOIR DOCUMENTS COMPLETS EN ANNEXE 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

Ainsi, les modifications apportées à la proposition initiale de la Commission concernent précisément les tests de toxicité chronique et larvaire, ainsi que la date initialement prévue pour la mise en œuvre des autres parties du document, remplacée par la phrase *« après la publication de la version révisée de l'EFSA GD »*. Exactement ce que le secteur agrochimique exigeait.

ÉPILOGUE

L'IMBROGLIO CONTINUE

Les citoyens et les associations de la société civile s'inquiètent de la vaste influence du secteur agrochimique sur les questions réglementaires, et sont consternés par l'énième obstruction de l'EFSA GD, qui résultera, de facto, par l'adoption de la proposition de *« compromis »* de la Commission.
La proposition actuelle de la Commission constitue une menace pour les pollinisateurs en Europe puisque, si elle est approuvée par le SCoPAFF, elle reportera à un futur dangereusement lointain l'adoption de tests clés pour protéger les pollinisateurs (la révision de l'EFSA GD prendra de fait plusieurs années).

Ces préoccupations sont partagées par le Parlement européen qui, dans une lettre à la Commission européenne signée par plus de 100 eurodéputés, a dénoncé une telle menace (voir annexe 10).

Dans sa réponse au Parlement européen (voir annexe 11), la Commission européenne (la commissaire européen à la santé, Vytenis Andriukaitis) a voulu se montrer rassurante en déclarant que :

« La Commission n'abaisse pas le niveau actuel de protection contre les risques chroniques pour les abeilles. Au contraire, (...) *grâce à la mise en œuvre des parties relatives aux risques aigus de l'EFSA GD, y compris l'évaluation des différentes voies d'exposition et les nouvelles exigences pour les tests de niveau supérieur, cette partie de l'évaluation des risques sera renforcée, tandis qu'il n'y aura pas de changement pour l'évaluation chronique avant la fin du réexamen mandaté à l'EFSA. Vous conviendrez avec moi qu'un tel progrès, même s'il est limité pour le moment, est préférable à la poursuite de l'imbroglio qui dure depuis 5 ans sur l'ensemble des lignes directrices. »*

De notre point de vue, cependant, il n'est pas question ici de *« progrès »*[21].

En effet, l'affirmation selon laquelle *« il n'y aura pas de changement pour l'évaluation chronique avant la fin du réexamen mandaté à l'EFSA »* signifie que des données sur la toxicité chronique peuvent continuer à être ignorées durant l'évaluation, comme c'est aujourd'hui le cas, alors même qu'elles existent[22].

Autre préoccupation : le réexamen annoncé de l'EFSA GD. Si une mise à jour de ce document est souhaitable, sa révision ne devrait ni modifier les orientations générales, ni ses objectifs de protection : les protocoles et les valeurs seuils de toxicité de l'EFSA GD sont fondés sur des données scientifiques incontestable et ont été établis par les meilleurs experts en Europe dans le cadre d'un

[21] Outre l'inclusion d'un plus grand nombre de voies d'exposition des insectes aux pesticides, une am lioration mineure.
[22] Cest exactement ce qui s'est pass lors de la r cente r valuation du thiaclopride : des donn es de toxicit chronique taient disponibles dans le dossier, mais elles n'ont pas t prises en compte car, selon le mod le actuel d' valuation (OEPP 170), dans le cas o les donn es de toxicit aigu ne montrent pas un risque majeur pour les abeilles, il n'est pas n cessaire de consid rer les donn es de toxicit chronique dans l' valuation du risque, m me si elles sont disponibles. Comme indiqu dans les conclusions de l'EFSA sur le thiaclopride (mars 2019, p. 16) : *« Des données de toxicité aiguë sur les abeilles domestiques étaient disponibles pour la substance active et les formulations représentatives. De plus, on disposait de données sur la toxicité chronique des abeilles domestiques adultes et de données sur la toxicité aiguë des larves. En ce qui concerne l'utilisation représentative sur le colza oléagineux, l'évaluation des risques a été réalisée conformément aux lignes direictrices SANCO sur l'écotoxicologie terrestre (Commission européenne, 2002a), c'est-à-dire que seules les données sur la toxicité aiguë pour les abeilles ont été prises en considération »*. En d'autres termes, l'heure actuelle, et probablement pendant de nombreuses ann es encore, des donn es de toxicit robustes sont et continueront d' tre ignor es alors m me qu'elles seraient disponibles. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5595

processus scientifique approfondi et transparent. À notre connaissance, il n'existe aucune preuve scientifique indiquant que ces taux de mortalité de fond et ces valeurs seuils soient inexactes. Seul l'industrie conteste aujourd'hui ces lignes directrices.

L'adoption de ces tests, et de l'EFSA GD en général, peut contribuer efficacement à enrayer la disparition des pollinisateurs en Europe. Mais compte tenu du rythme alarmant auquel disparaissent les populations d'insectes, chaque année compte. En reportant l'adoption de tests clés pour leur protection, tout en abaissant les objectifs de protection, le SCoPAFF et le Commission européenne perpétuent un *« imbroglio »* aux graves conséquences sur la biodiversité et le vivant, et à terme sur la sécurité alimentaire des Européens.

RECOMMANDATIONS

RECOMMANDATIONS POUR UNE RÉFORME DU SYSTÈME D'ÉVALUATION DES PESTICIDES

Les exigences en matière de données à fournir dans les études constituent la pierre angulaire de l'ensemble du système d'évaluation des risques.

Il est clair que le système d'évaluation des risques en place ne respecte pas le cadre juridique actuel et ne garantit pas une évaluation efficace des risques posés par les produits phytopharmaceutiques sur les pollinisateurs.

En réalité, l'évaluation européenne des risques posés par les PPP sur les abeilles est toujours effectuée selon des procédures obsolètes, produites par des institutions comme l'ICPPR avec des conflits d'intérêts démontrés. Ces procédures ne sont pas conformes au cadre juridique actuel, et leur champ d'évaluation limité ne tient pas compte de données significatives, même lorsqu'elles existent déjà, ce qui est incohérent si l'objectif réel est de protéger les espèces non ciblées. Comme spécifié dans le plan belge : *« d'un point de vue scientifique, il n'est pas acceptable d'ignorer les données robustes de toxicité disponibles sur les espèces non ciblées vulnérables, simplement parce qu'il n'y a pas de lignes directrices généralement admises en matière d'évaluation des risques »* (SPF 2018: 5).

À ce jour, seules les lignes directrices de l'EFSA prennent en compte l'ensemble des critères établis par le cadre réglementaire européen pour une évaluation satisfaisante des risques liés aux pesticides sur les abeilles domestiques, les bourdons et les abeilles solitaires. De plus, il s'agit de la méthodologie la plus complète à ce jour pour évaluer les risques posés par la nouvelle génération de pesticides (les pesticides systémiques).

Par ailleurs, l'EFSA GD a été conçu en respectant le principe de transparence, et en n'incluant que des contenus scientifiques indépendants, exempts de conflits d'intérêts, ce qui est primordial pour garantir des procédures solides et efficaces d'évaluation des risques pour l'environnement.

Nous estimons que l'adoption de ce document, mis à jour avec les derniers tests et résultats scientifiques disponibles, est absolument nécessaire pour traiter correctement la question de la dangerosité des pesticides pour les abeilles, et donc pour assurer la protection des insectes pollinisateurs en Europe.

Nous demandons donc à la Commission européenne et aux États membres d'adopter toutes les mesures nécessaires pour :

1. Soutenir la mise en œuvre immédiate de l'ensemble de l'EFSA GD, ou au minimum, de soumettre au vote des Etats membres lors des prochaines réunions du SCoPAFF la proposition de juillet 2018 de la Commission européenne, qui inclut les tests de toxicité chronique et larvaire.

2. Financer et conduire des programmes de recherche afin d'accélérer l'élaboration des méthodologies d'essais et des protocoles qui ne sont pas encore disponibles, tout en conservant les valeurs seuils de toxicité retenues dans la version actuelle de l'EFSA GD, à moins que des données scientifiques ne prouvent leur inexactitude. L'EFSA GD devrait être amélioré à l'avenir afin de prendre en compte d'autres sources potentielles de risque (par exemple, les mélanges de pesticides non intentionnels), ainsi que d'autres espèces de pollinisateurs.

3. Analyser les raisons et les éventuels conflits d'intérêts qui continuent de bloquer l'application de ces protocoles. Les autorités européennes devraient reconnaître qu'il s'agit là d'un problème d'intérêt public supérieur, comme l'a souligné la médiatrice européenne.

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LISTE DES ANNEXES

1. Réponse de la Direction générale de la santé et de la sécurité alimentaire à une demande de documents mentionnant l'EFSA GD.

2. Recommandation de la médiatrice européenne relative à la plainte 2142/2018/TE portant sur le refus de la Commission européenne d'accorder l'accès aux positions des États membres sur les lignes directrices relatives à l'évaluation des risques liés aux produits phytopharmaceutiques pour les abeilles.

3. Lettre (mars 2017) de l'ECPA aux membres du SCoPAFF.

4. Essais obligatoires et facultatifs - procédure belge d'homologation (tableau).

5. Lettre (décembre 2018) de l'ECPA aux membres du SCoPAFF.

6. Ordre du jour du SCoPAFF mentionnant l'EFSA GD (2013-2019).

7. Minutes de la réunion ad-hoc du Groupe consultatif sur la chaîne alimentaire, la santé animale et végétale, consacrée aux produits phytopharmaceutiques le 21 septembre 2018 à Bruxelles.

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).

9. Lettre (juillet 2018) de l'ECPA aux membres du SCoPAFF.

10. Lettre de Bart Staes et de +100 eurodéputés cosignataires sur la mise en œuvre de l'EFSA GD au commissaire européen à la santé, Vytenis Andriukaitis.

11. Réponse du commissaire européen à la santé, Vytenis Andriukaitis, à la lettre de Bart Staes et des +100 eurodéputés.

ANNEXE 1
Réponse de la Direction générale de la santé et de la sécurité alimentaire à une demande de documents mentionnant l'EFSA GD.

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
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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).

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

Liste des documents dont l'accès a été refusé à Pollinis par la Commission européenne

Electronically signed on 03/05/2018 11:52 (UTC+02) in accordance with article 4.2 (Validity of electronic documents) of Commission Decision 2004/563

European Ombudsman

Emily O'Reilly
European Ombudsman

ANNEXE 2
Recommandation de la médiatrice européenne relative à la plainte 2142/2018/TE portant sur le refus de la Commission européenne d'accorder l'accès aux positions des États membres sur les lignes directrices relatives à l'évaluation des risques liés aux produits phytopharmaceutiques pour les abeilles.

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].

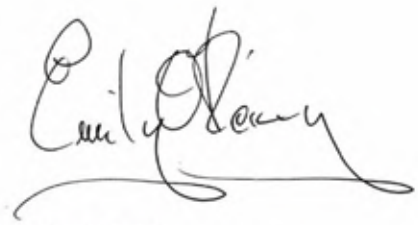
49. The Ombudsman therefore finds that the Commission's refusal to grant public access to the positions of Member States on the draft bee guidance constituted maladministration, in line with the considerations and principles explained above. She therefore recommends as below, in accordance with Article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

ANNEXE 3
Lettre (mars 2017) de l'ECPA aux membres du SCoPAFF

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.

ANNEXE 4
Essais obligatoires et facultatifs - procédure belge d'homologation (tableau).

EFFET TESTÉ	PROTOCOLE
Toxicité orale aiguë pour les abeilles domestiques	OCDE 213 GD : Abeilles domestiques, essai de toxicité orale aiguë
Toxicité orale aiguë pour les bourdons	OCDE 247 GD: Bourdon, essai de toxicité orale aiguë (octobre 2017)
Toxicité de contact aiguë pour les abeilles domestiques	OCDE 214 GD: Abeilles domestiques, essai de toxicité de contact aiguë
Toxicité de contact aiguë pour les bourdons	OCDE 246 GD: Bourdon, essai de toxicité de contact aiguë (octobre 2017)
Toxicité chronique pour les abeilles domestiques	OCDE 245 GD: Test de toxicité chronique pour les abeilles domestiques (alimentation pendant 10 jours) (octobre 2017)
Effet sur le développement des abeilles domestiques et les autres stades de développement (toxicité larvaire)	OCDE 239 GD : Test de toxicité larvaire pour les abeilles domestiques en exposition répétée
Essais en cage et tunnel pour les abeilles domestiques (si les précédents essais n'ont pas permis de démontrer l'innocuité du produit)	EPPO Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees
Essais sur le terrain avec des abeilles domestiques	EPPO Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees

*Essais facultatifs (aucune directive d'essai convenue ou finalisée n'est disponible)**

EFFET TESTÉ	PROTOCOLE
Effets sur les larves d'abeilles domestiques	Oomen PA, de Rujiter A et van der Steen J, 1992 // OCDE 75 GD : Test sur couvain d'abeilles domestiques dans des conditions semi-naturelles
Toxicité chronique pour les bourdons et les abeilles solitaires	OCDE 245 GD : Test de toxicité chronique pour les abeilles domestiques (alimentation pendant 10 jours) (octobre 2017) adapté aux bourdons et aux abeilles solitaires
Toxicité orale et de contact aiguë pour les abeilles solitaires	OCDE 213 GD, version adaptée : Abeilles domestiques, essai de toxicité orale aiguë. Directrice 214 de l'OCDE adaptée : Abeilles domestiques, essai de toxicité de contact aiguë
Effet sur le développement des bourdons/abeilles solitaires et autres stades de développement (toxicité larvaire)	- bourdons : OCDE 239 GD, version adaptée, Test de toxicité sur les larves d'abeilles domestiques après une exposition répétée - abeilles solitaires : annexe Q, EFSA GD (Toxicité orale pour les larves)
Essais en cage et tunnel sur des bourdons et des abeilles solitaires (si les précédents essais n'ont pas permis de démontrer l'innocuité du produit)	- bourdons : Tasei et al., 1993. // OCDE 75 GD, version adaptée : Test sur couvain d'abeilles domestiques (apis mellifera l.) dans des conditions semi-naturelles. - abeilles solitaires : Ladurner et al., 2008.
Essais au champ avec des bourdons et des abeilles solitaires (si les précédents essais n'ont pas permis de démontrer l'innocuité du produit)	- bourdons : annexe P, EFSA GD. - abeilles solitaires : Torchio, 1973.

* Des tudes sur la toxicit chronique pour les bourdons ainsi que des tudes sur les abeilles solitaires sont galement en cours de d veloppement, mais encore un stade pr matur .

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)

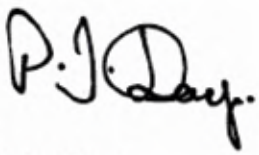
While we support the Commission's commitment to put harmonised risk indicators in place, we are concerned that the proposed indicators (based on sales statistics and number of products approved under Article 53 of Regulation 1107/2009) combined with arbitrary weighting factors, will not on their own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

ANNEXE 6
Ordre du jour du SCoPAFF mentionnant l'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.

ANNEXE 7
Minutes de la réunion ad-hoc du Groupe consultatif sur la chaîne alimentaire, la santé animale et végétale, consacrée aux produits phytopharmaceutiques le 21 septembre 2018 à Bruxelles.

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.

[...]

ANNEXE 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 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
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	
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~~	

9

	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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10

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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12

			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)

13

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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14

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

15

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.

ANNEXE 9
Lettre (juillet 2018) de l'ECPA aux membres du SCoPAFF.

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.

ANNEXE 10
Lettre de Bart Staes et de +100 eurodéputés cosignataires sur la mise en œuvre de l'EFSA GD au commissaire européen à la santé, Vytenis Andriukaitis.

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
Michèle RIVASI
Ernest URTASUN
Jakop DALUNDE
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Carolina PUNSET
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Miguel VIEGAS
Jaoa FERREIRA
Joao PIMENTA LOPES

ECR
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.

ANNEXE 11
Réponse du commissaire européen à la santé, Vytenis Andriukaitis, à la lettre de Bart Staes et des +100 eurodéputés.

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

À PROPOS

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