From: SANCO CONSULT-E3
To: SANCO CONSULT-E3
Cc: [redacted] (SANCO); [redacted] (SANCO); [redacted] (SANCO)
Subject: FW: ECPA Comments on EFSA Guidance Document on the Risk Assessment of PPPs in Bees
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ECPA Position on EFSA Guidance Document on the RA of PPPs on bees.pdf
23236_ECPA letter on the new EFSA Bee GD.pdf
Importance: High

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From: [redacted] (SANCO)
Sent: Wednesday, September 18, 2013 1:11 PM
To: SANCO CONSULT-E3
Subject: FW: ECPA Comments on EFSA Guidance Document on the Risk Assessment of PPPs in Bees
Importance: High

Pls reg and assign to [redacted] as CF, [redacted] and [redacted] for INFO

From: [redacted] [mailto[redacted]@ecpa.eu] **On Behalf Of** [redacted]
Sent: Wednesday, September 18, 2013 1:00 PM
To: [redacted] (SANCO)
Cc: [redacted] (SANCO); [redacted] (SANCO); [redacted] (SANCO); [redacted] (CAB-BORG); [redacted]@gov.si; [redacted]@bmelv.bund.de; [redacted]@jordbruksverket.se; [redacted]@minrol.gov.pl; [redacted]@bmelv.bund.de; [redacted]@msz.gov.pl; [redacted]@agriculture.gouv.fr; [redacted]@dfa.ie; [redacted]@minbuza.nl; [redacted]@dfa.ie; [redacted]@agriculture.gouv.fr; [redacted]@land.gov.sk; [redacted]@ansvsa.ro; [redacted]dfa.ie; [redacted]@svssr.sk; [redacted] (SANCO); [redacted]@hse.gsi.gov.uk; [redacted]@sanita.it; [redacted]@agriculture.gov.ie; [redacted]@dgadr.pt; [redacted]@hse.gsi.gov.uk; [redacted]@tukes.fi; [redacted]@dfa.ie; [redacted]@madr.ro; [redacted]@msssi.es; [redacted]@agri.ee; [redacted]@agriculture.gouv.fr; [redacted]@agriculture.gov.ie; [redacted] (SANCO); [redacted]@ctgb.nl; [redacted]@bvl.bund.de; [redacted]@vaad.gov.lv; [redacted]@msa.org.mt; [redacted]@mattilsynet.no; [redacted]@magrama.es; [redacted]@msz.gov.pl; [redacted]@pma.agri.ee; [redacted]@mgszh.gov.hu; [redacted]@agriculture.gouv.fr; [redacted] (SANCO); [redacted]@reper-portugal.be; [redacted]@minszw.nl; [redacted]@msa.org.mt; [redacted]@vatzum.lt; [redacted] (EFSA); [redacted]@diplomatie.gouv.fr; [redacted]@sgae.gouv.fr; [redacted] (SANCO); [redacted]@gov.si; [redacted]@kemi.se; [redacted]@pzh.gov.pl; [redacted]@vatzum.lt; [redacted]@vaad.gov.lv; [redacted] (SANCO); [redacted]@kemi.se; [redacted]@da.moa.gov.cy; [redacted] (EFSA); [redacted]@health.fgov.be; [redacted]@mae.etat.lu; [redacted]@minrol.gov.pl; [redacted]@mmediu.ro; [redacted] (SANCO); [redacted]@hse.gsi.gov.uk; [redacted]@uksup.sk; [redacted]@gov.si; [redacted]@lebensministerium.at; [redacted]@magrama.es; [redacted]@magrama.es; [redacted] (SANCO); [redacted]@srs.cz; [redacted]@bmelv.bund.de; [redacted]@asta.etat.lu; [redacted]@ctgb.nl; [redacted]@MST.DK; [redacted]@mfa.gov.lv; [redacted]@diplomatie.gouv.fr; [redacted]@sanita.it; [redacted] (SANCO); [redacted]@gov.mt; [redacted]@pest.srs.cz; [redacted]@efsa.europa.eu; [redacted]@kemi.se; [redacted]uksup.sk; [redacted]@nsrz.government.bg; [redacted]@vaad.gov.lv; [redacted]@sanita.it; [redacted]@ages.at; [redacted]@bvl.bund.de; [redacted]@kemi.se; [redacted]@minlnv.nl; [redacted]@mattilsynet.no; [redacted]@ages.at; [redacted]@minagric.gr;

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Subject: ECPA Comments on EFSA Guidance Document on the Risk Assessment of PPPs in Bees
Importance: High

Dear [redacted],

I am writing to you to inform you of ECPA's concerns regarding EFSA's Guidance Document on Risk Assessment of Plant Protection Products on bees. ECPA welcomed the opportunity to provide comments directly to EFSA during the consultation process and the information session organised by EFSA but we would like to stress the consequences of using this document on the registration of plant protection products in Europe.

I enclose a letter detailing our concerns and possible suggestions.

Overall, we believe the suggested risk assessment results in over complexity and conservatism, without demonstrating an added value to bee health and it would lead to a less robust risk assessment, putting in place significant hurdles to the risk management decision process.

Taking into account the conservatism of the first tier and the unachievable recommendations for higher tier tests, it is our belief that it will be almost impossible to register any new or existing insecticides in Europe and the regulatory hurdles will be unnecessarily high for herbicides and fungicides unless this guidance changes significantly.

We remain at your disposal if you have any questions. We would of course welcome the opportunity to discuss this with you directly.

Kind regards.

[redacted]

[redacted]

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European Crop Protection

ECPA's position on the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

Brussels
2 September 2013
[redacted]/13/[redacted]23237

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Key messages :

- There is no evidence which positively demonstrates that the proper use of pesticides is having any impact on bee populations. **EFSA has completely overlooked the other factors affecting bee populations** (such as viruses, pathogens, nutrition factors,…)
- The guidance is **overcomplicated** and overly **conservative** in its risk assessment assumptions, which makes it **impractical** and **unrealistic.**
- Overall, the protection goals **lack practical feasibility and measurement** as well as **relevance** to bee health and (e.g. no proof that a 7% reduction of colony size is biologically relevant)
- We estimate that the screening tier risk assessment would lead **90%** of all substances for honey bees and **100%** for bumble and solitary bees to fail the first tier. The EFSA guidance lacks focus and therefore it fails to distinguish effectively which substances merit higher tier testing.
- **Higher tier tests are not feasible** as stipulated in the guidance.
- The guidance should be checked against criteria such as **practicality** and **usability** for Member States and applicants.
- Some of the new required studies rely partly on **non-validated methodologies** and **lack internationally validated** test guidelines (OECD, EPPO, FIFRA, OPPTS).
- There is **not enough capacity** in Europe to run the required studies.
- The **cost for development** of a product will be increased, therefore creating economic hurdles for innovation (potentially fewer niche products, with remaining products being less adapted for a crop).
- **We believe that it will be almost impossible to register any new or existing insecticides in Europe and the regulatory hurdles will be unnecessarily high for herbicides and fungicides unless this guidance changes significantly.**
- **Industry considers that this document would produce a lack of robustness in the risk assessment which will set serious hurdles to risk management decisions.**
- **Industry proposes[1] Commission and Member States to delay the adoption of the guidance in order to revise it, ensuring its practicability and consistency with the EU regulatory framework and in consultation with relevant international organisations (e.g. OECD, EPA,…).**

[1] Detailed proposals on page 9 and 10.

ECPA's position on the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

1. Introduction

On the 4th of July EFSA published the final version of its Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera, Bombus* spp*. and solitary bees*).
ECPA supports the development of a tiered approach and of the methodology to consider most of the issues currently being debated in literature and in the media. We also acknowledge the fact that EFSA had limited time and resources to develop the guidance and to review existing data. However, this final guidance takes a highly conservative approach which is a major concern for the Industry. ECPA and other stakeholders provided many comments during the two public consultations and EFSA has now clarified several points but it is disappointing to see that critical issues are not addressed and the complexity of the document has even increased. very little has changed or positively evolved since then.

In this document we summarize the main points of concern and also highlight issues within the document in relation to, protection goals, risk assessment, testing methods and new data requirements, exposure, barriers to adoption and implementation, inconsistency with other Guidance Documents and present conclusions and proposals which aim at how to resolve the issues using existing expertise as well as knowledge being/to be generated in expert groups on pollinators.

We believe that in its current form the guidance document is not suitable and applicable for any regulatory use but that with discussion and additional work a useable framework for risk assessment of pollinators can be developed and implemented.

In summary:

- Overall the guidance document is confusing to work with and contains many inconsistencies and errors. As a guidance document it is not precise enough in many cases when it comes to definitions, but is highly demanding in what to achieve and fulfil.

- The document is extremely complex. For instance an assessor may have to calculate 48 different HQ/ETRs in the initial screening tier and many more calculations will be necessary at tier I where elements such as exposure to in-field weeds, field margins, adjacent crops and non-*Apis* species will be required.

- New testing requirements listed in the guidance, cannot not be achieved at this time; these include tier I laboratory studies for which there are no recognised or validated guidelines. Making meeting the data requirements extremely difficult.

- There is a lack of data supporting the numerous assumptions which together with the suggestions as regards testing lead to considerable and possibly unnecessary additional safety factors, culminating in an unnecessarily over conservative risk assessment scheme.

- An assessment of the screening tier risk assessment leads to 90% of substances for honey bees and 100% for non-*Apis* bees (using available honey bee endpoints with the required additional safety factor) failing the first tier.

- Higher tier tests are over complicated to the point where they cannot be conducted to the standards required by EFSA consequently making the conduct of a higher tier risk assessment virtually impossible.

- The guidance contains several misconceptions in the definition of the level of protection considered. As a consequence, this risk assessment and more particularly the screening step actually fails to discriminate substances of negligible concern from substances of possible concern.

- The implementation of the guidance document would immediately require the execution of many laboratory studies on honey bees, *Bombus* spp. and solitary bees for active substances, metabolites and formulations. In addition due to many substances being unable to pass the initial risk assessment this would necessitate the requirement for many higher tier studies (field and semi-field). Currently there is a lack of testing resources and such a testing programme would need many years for implementation. This would mean that in many cases it would not be possible to even conduct the necessary tests to meet the requirements of the guidance document.

- A full impact and sensitivity analysis is necessary for the guidance document, which should check the ability of this risk assessment scheme to identify products of concern triggering a refined risk assessment and/or risk mitigation measures. This sensitivity analysis is critical in order to avoid that a significant number are even temporarily "*put in infraction*" as regards protection goals and the law.

- Whilst a large majority of the products put through the assessment fail the first tier this might leave the impression that many will eventually pass at higher tiers by just carrying out more studies and spending more money. Considering the lack of regulatory guidelines for non-*Apis* bees and that recommendations for higher tier (especially field tests for honey bees) are virtually unachievable, **we believe that it will be almost impossible to register any new or existing insecticides in Europe and the regulatory hurdles will be unnecessarily high for herbicides and fungicides unless this guidance changes significantly.**

➔ **Industry considers that this document would produce a lack of robustness in the risk assessment which will set serious hurdles to risk management decisions.**

2. Definition of protection goals

ECPA expert comments provided during the consultations on the relevance of selected protection goals have been mainly ignored because it was a risk manager's decision.

As an example it is clear that the demand to measure the biomass and colony strength of honey bees is not feasible in practice. The abundance of individuals in a bee colony is strongly dependent on apicultural practices, i.e. from modifications that a beekeeper induces in a colony.
Therefore it is questionable how relevant this is as a protection goal. EFSA claims it is feasible without giving any indication on how to do it. Also the relation to colony viability is not established.

Another example is the goal to prevent a 7% reduction of colony size. It is still questionable how far such a reduction is at all biologically significant. According to experience, greater

differences of colony strength of one and the same colony (e.g. of a control group) from one weekly assessment to the next are not uncommon. Also local conditions can affect measurements so if there is cool wet weather at the control site but not at the test site (which needs to be separated by several km from the control site) this can cause observed differences which are due to the multiple stressors and conditions at assessment or due to site rather than due to the test material (single stressor).
Although specific protection goals are mentioned in the guidance document (e.g. less than 7% reduction in colony strength), we believe there is a lack of legal basis to use the suggested ETR values for decision making and the values have not as such been debated by risk managers, or other stakeholders, in light of their screening value and use in risk assessment.
Overall, the protection goals lack relevance to bee health and practical feasibility and measurement.

3. Risk assessment

Overly conservative trigger values

The assumptions behind the proposed trigger values for both acute and chronic risk for honey bees and the levels of dietary exposure suggested by EFSA are highly conservative and are unnecessarily stringent for the proposed tier I risk assessment of honey bees.

An impact assessment of the EFSA guidance revealed that the suggested tier I will fail its screening purpose and lead a majority of products into higher tier testing. Of the approximately 160 products put through the assessment, 90% for honey bees and 100% for *non-Apis* bees (using available honey bee endpoints as surrogate, with additional safety factor as required by the EFSA guidance) would fail the first tier. The majority of these substances were of low bee toxicity such as herbicides and fungicides (See Table 1).

Table 1: Risk to honey bees, screening tier assessment % of uses passing the risk assessment based on 163 uses.

	Acute risks to honey bees				Chronic adult honey bees	Chronic larvae* honey bees
Chemical group	HQc (current)	HQc (new)	HQo (current)	ETRo (new)	ETR	ETR
Herbicides	91	98	94	88	15	100
Fungicides	98	100	96	92	6	100
Insecticides	47	47	40	40	6	76
Other	100	100	88	88	100	100
all	81	82	78	74	8.64	93
* NOEC for larvae estimated as 1/10 of adult's LC50						
Additional safety factors and lower trigger values for bumble bees (up to 63x) and solitary bees (up to 56x) leading to 100% failure at tier 1						

Non-Apis bees

Despite EFSA answers to our comments and questions there is still no scientific basis to make the comparison between effects on honey bee and bumble bee colonies (extra factor of 5 and 10 although not supported by data), and especially to extrapolate it to solitary bee population sizes.

Inapplicable Bumble bees & solitary bees schemes

It is a well-established principle in risk assessment to use sentinel test species. The honey bee is a suitable test species and other pollinators are already covered by the honey bee and the non-target arthropods risk assessment. If products have a safe use concerning NTAs (including Hymenoptera) this should be considered in the risk assessment, especially where full fauna field studies have been conducted.

For bumble bees and solitary bees, the first tier risk assessment has a higher level of conservatism than for honeybees (e.g. due to differences in exposure – non-*Apis* species do not exploit agricultural crops as efficiently as honeybees due to lack of communication behaviours and therefore are less exposed to pollen and nectar). Using honeybee endpoints with a safety factor of 10 coupled with lower trigger values leads to a situation 50 to 60 times more conservative than for honeybees.

➔ **As a consequence, it is foreseen that no insecticide can pass the guidance document requirements for an acceptable risk assessment.**

Assessment regarding solid applications

The proposed scheme for granules and seed treatment has become extremely complex since the original draft version. In addition further dialogue at the EU level is required as the guidance does not consider existing differences between member states on the number of seeds per unit, the number of units per ha and the difference in drilling materials. Overall this means that risk assessments for such products are not valid or useful.

4. Testing, test methods and new data requirements

Non-validated test methods

Many key studies in the risk assessment scheme of the EFSA guidance document are not available as test guidelines by internationally recognized testing guidelines organisations (OECD, FIFRA, OPPTS, EPPO) or even as ring tested methods in development:

- laboratory chronic toxicity study on adult honey bees,
- laboratory study on honey bee hypopharyngeal gland development,
- laboratory study on honey bee larvae full life cycle,
- accumulative toxicity study (formerly called bioaccumulation),
- semi-field test according to EFSA requirements,
- field test according to EFSA requirements.

Many of the new testing listed in the guidance will be difficult to achieve without proper guidelines; these include tier I studies which require investigations of potential effects on honey bee hypopharyngeal glands (which is essentially a tier I histopathological endpoint for an invertebrate species) and accumulative potential (similar to bioaccumulation). Full life cycle honey bee larval development tests are specified even though the current state of the

sciences indicates that this methodology cannot proceed beyond pupation without excessive control mortality.
In addition tests on bumble and solitary bees (laboratory, semi-field, and field studies) would be necessary, to avoid overly conservative additional safety factors, and these are not part of the data requirements identified by SANCO following the advice of the dedicated expert group.

Lack of testing resources

Current contract research laboratory capacity and expertise is also highly limited, especially in regards to the recommended studies for which there are no validated and recognised test methods.
Most test methods are not validated and recognised guidance is not available. Laboratory testing capacity and expertise also needs to 'catch-up' with needs. This will take several years. In addition the huge number of studies that are expected to be triggered by the guidance under the proposed schemes/requirements will be logistically extremely challenging if not impossible and lead to considerable delays in approvals.
In addition, it cannot be guaranteed that such tests can be performed with the level of confidence and certainty necessary to perform a risk assessment.

➔ **Until validated and internationally recognized test guidelines are available, current testing methodologies should be considered together with risk assessment procedures which have proven to be effective**. There will need to be a synchronized timeline for implementation of the guidance document which will take many years.

EFSA itself considers that availability of test laboratories is a matter of timeline for implementation of the guidance document and a risk management issue not within their remit.

➔ **ECPA believes that due to the lack of validated study guidelines on bees and solitary bees there are little or no options to further refine and improve the field reality of the regulatory risk assessment**.

Unrealistic Field/Semi-field studies recommendations

The recommendations of how semi-field and field testing should be conducted are unrealistic, with too many paths to follow in parallel in assessing the risk via the various exposure routes, rather than defining worst case scenarios which would cover certain other cases.

Due to the on-going work by the International Commission on Plant-Bee Relationships (ICPBR) on revising the existing EPPO semi-field and field test guidelines, and especially the work being done on improving the sensitivity and robustness of the test guidelines, **ECPA recommends that the EFSA Guidance Document should refer to the revised ICPBR Test Guidelines once available:**

1. Rather than trying to quantitatively measure and maintain 90th %tile exposure in semi-field and field studies, ECPA proposes that such studies should:
    - be conducted using the relevant Good Agricultural Practices (application rate and timing) that needs to be covered in the risk assessment.
    - include residue measurements, taken from pollen and nectar during the study to consider exposure of the bees during the trials.
    - be based on a trial site selected to avoid as far as possible alternative bee forage.
    - It is emphasized that 90th %tile exposure relates to the level of exposure and does not correlate to the 90th %tile probability of occurrence of such

exposure. Indeed EFSA state in their document that at tier I they exceed the 90th %tile exposure level.

2. In order to improve the robustness and sensitivity of honey bee field trials ECPA recommends that at least 2 to 3 independent field studies be conducted.

3. In case of remaining concerns following the conduct of such field studies and the resulting risk assessment, the ECPA recommendation is to consider post-approval monitoring of real apiaries located in their natural locations (i.e. not moving hives next to field artificially) but within agricultural areas where the product will be used.

5. Exposure

Exposure assessments for different types of plants sampled by the bees

The document still includes the misleading statement that 90th%-ile exposure protects 90% of the hives at the edge of the field. For bees which naturally need to forage on a range of different plants to acquire their nutritional requirements (i.e. various amino acids in pollen) it is unrealistic to assume that 100% of the colony energetic and dietary requirements can be met by a single type of crop plant. Consequently when taking into account high and unrealistic food consumption values exposure is greatly over estimated in the risk assessment.

In addition in higher tier tests there is a need to consider difference between various plants which are visited by bees (e.g. different weeds and crop). It is highly questionable in how far it is realistic or even necessary to generate PECs for all plant species on which bees may forage in a certain area. This requirement does not appear realistic under European conditions and there's still no guidance provided on how to produce a practicable refined risk assessment.

6. Barriers to implementation and adoption

Implementation timeline

There are many new data requirements included in the guidance document. If implemented there will be need for an agreed policy on how and when to implement this new guidance and it is the view of ECPA that this can only happen after the guidance has been thoroughly revised. It is impossible at present to implement the guidance immediately as time is required to plan, conduct and report new studies and in many cases actually develop test methods where no standard methods already exist. For example, at least 2-3 years is required in order to plan, conduct and report a new field study.

Although specific protection goals are mentioned in the guidance document (e.g. less than 7% reduction in colony strength) we believe there is a lack of legal basis to use the suggested ETR values for decision making and the values have not as such been debated by risk managers, or other stakeholders, in light of their screening value and use in risk assessment.

The document in its current state is not applicable for regulatory decisions and would raise many questions or uncertainties delaying the process without providing any additional safety for bees.

7. Inconsistency with other Guidance Documents from other EFSA working groups

The document contains several inconsistencies with other EFSA guidance documents. As an example, in the bee guidance document it is assumed that all spray deposit not on the crop is deposited on plants (e.g. like weeds), whereas assumptions for ground water consider no or negligible interception of sprays even on growing crops. These assumptions make the outcome of risk assessment difficult to interpret for decision making.

8. Industry proposals

The following proposals aim at illustrating how to resolve the issues using existing expertise as well as knowledge being/to be generated in expert groups on pollinators:

- The conservatism adopted in developing the guidance document relies on the lack of data available to EFSA as well as the lack of time given to EFSA to collect and analyse available data, as for example on exposure levels or scenarios. The importance of the issue and of the consequences of the current level of conservatism on the risk assessment process fully justify the need to give experts the time to proceed to the necessary data collection. This could be organised through a **call for data being available in industry, regulatory authorities and research laboratory**;

- Similarly, exposure scenarios have been built on the basis of theoretical approaches focusing on honey bees, bumble bees and solitary bees, with no cross check of existing approaches developed in other guidance documents. **A check for consistency with other guidance documents is necessary.** As an example, the consultation of the EFSA guidance document on birds and mammals would bring directions on how the tiered approach was built for birds, which currently covers similar issues such as the diversity of exposure routes (the risk assessment to birds allows to cover various bird diets and exposure through water into 5 risk quotients (for the screening part) where 48 risk quotients are proposed for the honey bee). This would allow a simplification of the risk assessment scheme and avoid diverting from the uniform principles;

- **A check for consistency with the regulation is also necessary.** Indeed Annex to Sanco 11803 indicates testing on additional pollinator species, should rely on the demonstration that exposure through other routes than contact occur ("Where for particular arthropods (such as pollinators and herbivores) testing conducted in accordance with points 10.3.1 and 10.3.2.1 to 10.3.2.4 is not appropriate, additional specific testing shall be required, where there are indications that exposure by routes other than by contact occur (for example plant protection products containing active substances with systemic activity)." The guidance document should therefore give guidance on how to determine that the exposure of bumble bees or solitary bees may not be covered by the exposure scenarios used for the honey bee or other arthropod species.

- **A consultation of MS is necessary on legal issues related to protection goals as well as the implementation of test methods being not covered by internationally accepted test guidelines:**
    - The current translation of protection goals having been discussed with risk managers into ETRs and HQ trigger values leads to 100% of active substances failing the tier 1 risk assessment and this should be discussed in light of a proper impact analysis.
    - The implementation and use of non-internationally adopted test guidelines raises several difficulties, regarding the validity of the studies that are to be

generated before the adoption of relative test guidelines and regarding the weakness of the resulting risk assessment;
    - Therefore the consultation of organisations being involved in the development of testing guidelines (OECD, ICPPR) is necessary in order to guarantee the robustness of the methods to be used and evaluated by MS

- **The calendar of implementation of the recommendation laid down in the guidance document should rely on a transparent consultation of testing resources in Europe,** in order to not put industry into the infraction of not being able to respect requirements;

- The suitability for decision making should again be discussed with end users and MS.

European Crop Protection

[redacted]/13[redacted]/23236
17 September 2013

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European Commission
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Dear [redacted]

Our industry strongly believes that bees and their role in agriculture and nature are highly important; we have a great interest in having healthier bees in Europe and we are fully committed to contributing to this end, within a framework which is founded on solid science, robust evidence and a proportionate risk-based approach. However, we believe that the recently published EFSA Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera, Bombus spp. and* solitary bees), fails to meet those principles and rather would lead to greater complexity without improving bee health.

Within the guidance document, we support the developed tiered approach and the methodology suggested for considering most of the issues currently being debated in literature. However, even after an extensive redrafting process and a public consultation with more than 1000 comments received from various stakeholders very little has evolved and the document remains unsuitable for regulatory use. The document is overly complex, contains numerous inconsistencies and unproven assumptions - and proposes extremely conservative risk assessment schemes without bringing additional safety to bees.

It should also be highlighted that the EFSA document in its current state is disconnected from the requirements in Regulation 1107/2009 and its implementing Regulations on data requirements and the uniform principles. We would in particular highlight:

- New testing listed in the guidance such as tests investigating potential effects on hypopharyngeal glands, test to determine accumulative potential, tests (laboratory, field, combined laboratory to field studies) on bumble bees and solitary bees, are not part of the data requirements.
- There is no legal basis to use the suggested ETR for decision making.

Industry considers that this document would lead to a less robust risk assessment, putting in place significant hurdles to the risk management decision process.

The EFSA Guidance document establishes overly conservative risk assessments in tier I. The tier I testing and risk assessment should be a screening step to select some substances or products for further testing. However, an impact analysis shows that the majority of compounds require higher tier tests following this tier 1 assessment (90% of the active substances for honeybees and 100% for bumbles). The inclusion of new exposure routes and their theoretical conservative approach worsen the situation furthermore. A synthesis of this impact analysis is included in the ECPA detailed position attached to this letter and the final impact assessment will be made available in the near future.

Whilst a large majority of the products put through the assessment fails the first tier this might leave the impression that many will eventually pass at higher tiers by just carrying out more studies and spending more money. **It is our understanding that unless this guidance changes significantly it will be almost impossible to register any new or existing insecticides in Europe, mainly because there are no regulatory guidelines for non-Apis bees and the recommendations for higher tier (especially field tests for honey bees) are virtually unachievable.**

Like for the draft version of the guidance, such volume of new data could not be generated in the short term with the current European capacity of Good Laboratory Practices certified laboratories. It will also require products to be tested on a huge number of colonies.

Nevertheless, ECPA acknowledges the proposed EFSA recommendations relative to existing test guidelines and for further testing methodologies. ECPA believes that these recommendations need to be evaluated by experts in testing methodologies dedicated to honey bees and pollinating species so that consolidated methods are proposed by organisations in charge of developing harmonised testing guidelines (i.e. OECD, ICPPR, OPPTS). This step is critical to maintain the confidence in the data being generated for regulatory purpose and used in support of decision making. By suggesting new tests without considering their feasibility this document will put applicants and authorities out of bounds and in a situation to not fulfil their legal obligations.

ECPA believes that EFSA raised many interesting but highly theoretical scientific questions, without justification on their relevance for honeybees, bumblebees or solitary bees health in the field. Given the complexity and the outstanding issues linked to this document, there is a need for careful consideration and further revision.

Using this document as a basis, ECPA would suggest the creation of a working group of actual Risk Assessors from Member States authorities tasked with the creation of a workable framework to support a predictable zonal PPP assessment process.

We would welcome the opportunity to meet with you to provide any further information as needed.

Kind regards,

[redacted]

[redacted]

[redacted], [redacted] ECPA

Cc: [redacted]

Standing Committee members