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HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

Workshop on EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees

(*Apis mellifera*, *Bombus* spp. and solitary bees)

HOTEL BRISTOL STEPHANIE, Brussels, 11 and 12 December 2013

DRAFT
SUMMARY REPORT

The comments expressed at this meeting represent the position of the participants and the different services of the European Commission but may not necessarily represent the opinion of the Commission.

Acknowledgement: Substantial financial and organisational support was provided by the Netherlands. Case studies were prepared in advance of the workshop by 5.1.2.e (France), 5.1.2.e (Germany), 5.1.2.e (the Netherlands) and 5.1.2.e (United Kingdom). The same experts were also rapporteurs of breakout groups. Introductory presentations were given by 5.1.2.e 5.1.2.e and 5.1.2.e from the European Food Safety Authority (EFSA).

1. INTRODUCTION

Bees play an important role in natural and agricultural ecosystems through provision of pollination services and for food production.. Recent reports of global bee decline and associated impacts on pollination services are of a high concern for the society and the protection and management of bees is therefore very important. Bee declines are thought to be driven by multiple factors, one of which is proposed to be exposure to pesticides is proposed to be one. At the same time there is a need for 'safe' pesticides in agriculture.

In the framework of the European Food Safety Authority (EFSA) revision the European Guidance Document on terrestrial ecotoxicology elaborated by the Commission and experts from Member States, the European Commission (EC) asked EFSA to develop a new Guidance Document on the risk assessment of plant protection products for bees. The Guidance Document, published on 4 July 2013, is intended to provide guidance for industry and national authorities in the context of the review of plant protection products (PPPs) and their active substances under Regulation (EC) 1107/2009.

A large number of comments were submitted by Member States and stakeholders during the two open consultation rounds arranged by EFSA, and also after the publication of the Guidance Document. Appreciation and acknowledgement for the work of EFSA to develop this guidance: a necessary step in the needed refinement of the evaluation of risks to bees. Concerns were raised e.g. regarding the impact on availability of PPPs in the future, feasibility of conducting required studies, lack of agreed test guidelines, the complexity of the document and interpretation of study results in relation to the protection goals. Furthermore, the diverging views among Member States and different stakeholders that were evident from the decision process for the three neonicotinoids clearly showed the sensitivity of the topic. Therefore, the Netherlands proposed to organise a workshop preceding the 'take note' process in the Standing Committee on the Food Chain and Animal Health, with the scope of bringing risk managers and risk assessors from Member States together for the first time to discuss technical issues as well as risk management and the implementation of the Guidance Document.

Furthermore, with Regulation (EC) No 1107/2009, new "data requirements" for pesticide dossiers including the requirement to assess the impact of pesticides on bees were adopted. New studies will be required to address chronic and sub-lethal effects and to consider the risk to bumblebees and solitary bees.

The Workshop was attended by 45 experts from 23 Member States including Norway.

2. FIRST PLENARY SESSION

5.1.2.e (EFSA) presented the mandate to EFSA given by the Commission and the new items introduced compared to the previous risk assessment scheme (EPPO). He described the protection goal as agreed by risk managers, and how this was used to derive trigger values that would enable a risk assessment that would assure that this goal is met. It was emphasised that future refinement of first tier trigger values will be possible once more information becomes available on e.g. background mortality rates of forager bees, larvae mortality and effects on development of the hypopharyngeal gland in relation to impact on colony size. Trigger values could also be calibrated with field studies. EFSA considered it not possible to include other sublethal effects, such as behavioural effects, in the first tier assessment at this stage and the reasons of this were given. Elements in the scheme that contribute to a more or less conservative assessment were described and a pass/fall rate analysis for 33 substances was presented.

5.1.2.e (EFSA) explained the tiered approach of the risk assessment and the different input values. He showed how the short-cut values used in the assessment were derived and how the calculator developed by EFSA could be used to quickly and easily calculate hazard quotients (HQ) and exposure to toxicity ratios (ETR). This was exemplified with case studies. Data on residues in pollen and nectar was highlighted as key information to refine the assessment. It was also shown how a qualitative uncertainty analysis could be done.

The presentations were followed by a question and answer session. Issues discussed were related to the proposed use of effects on development of the hypopharyngeal gland as the only sublethal effect in the assessment scheme; how repeated applications could be dealt with; the possibility of extrapolating between different crops; possible exposure to residues in honeydew and the need for more semi-field and field effect studies.

3. SUMMARY OF DISCUSSIONS IN BREAKOUT GROUPS

3.1. Case studies and first set of questions

Two case studies were proposed for discussion in each breakout group (list of active substances analysed: XXXXXX). However, due to time constrictions, in some cases detailed discussions only took place for a single case.

Overall it was concluded that for honeybees the scheme works well. Specifically the screening steps and the first tier assessment can be applied easily. Some concerns were highlighted regarding the sublethal effects assessed with the hypopharyngeal gland tests (HPGs). In most case studies no data were available and therefore the risk could not be finalised. For bumblebees and solitary bees, the risk assessment fails in the screening steps and cannot be refined due to the lack of data.

The workload and the time needed to apply the new risk assessment scheme was one of the concerns highlighted by risk assessors from the National authorities. However when the same case studies were assessed using the EFSA Excel calculator, the time

needed was significantly reduced and it took (approximately 15 minutes to complete the scheme when the data are available).

Q1: Which parts of the guidance were clear enough and which parts of the guidance caused difficulties due to insufficient clarity or different interpretations?

Overall it was concluded that the following sections of the guidance looked clearand feasible:

- Calculations for screening and Tier 1 for all bees (Honeybees (HB), bumblebees (BB) and solitary bees (SB)).
- Refinement via residue data in nectar and pollen.

Other sections of the guidance would need further refinements in order to improve clarity:

- for puddle water, the scheme seems challenging to be applied due to the lack of the exposure concentrations. In addition it was pointed out that the approach/method used to calculate concentrations in puddles is inconsistent with the one used in the EFSA guidance document on the risk assessment for Bird and Mammals.
- for succeeding crops, the first tier appears difficult to calculate due to fact that the PEC-porewater is not a standard output from the exposure assessment. The concern raised for this approach is that the risk may be underestimated. In addition in higher tiers, it is difficult to assess which succeeding crops could be relevant.
- for plant metabolites the procedure seems very demanding and time-consuming. Some doubts were raised about the necessity to apply the scheme for all metabolites >0.01 mg/kg and in all plants. Therefore, it was proposed to include the calculation method from the Guidance Document on Birds and Mammals.

In addition, a detailed list of specific comments is reported below:

- Screening and first tier - standardized data not yet available for the following sections (HPG, accumulative risk, bumble bees, solitary bees).
- The terminology used for drift values related to the different application (downward, upward, sideward) was identified as a possible cause of confusion. Therefore it was proposed to link the drift values to the different crops. In addition, reference or tables presenting the drift values should be added in the document in order to allow experts to propose buffer zones as mitigation measures.
- For orchards, late and early applications should be related to the BBCH stage in order to avoid mistakes.
- More clarity is needed in the definition of field margins and adjacent crops. Questions were raised on the relevance of differentiation between these two scenarios.
- For granular application, some clarifications are needed for the assessment for the treated crop.
- It is proposed to add a list of crops that do not produce guttation droplets (need for more information as no data are available now) and to investigate the possibility of extrapolation, especially for minor crops.

- Deposition values need to be consistent with the Guidance Documents for seed treatment.

In general all the calculations appeared difficult to perform and the structure of the document was not considered very user-friendly. However, this issue could be improved as soon as the Excel calculator will be "ready to use".

Q2: Which parts of the guidance were easily followed and which parts of the guidance caused difficulties due to the complexity of the guidance requirements?

The structure of the document is too complex and would need simplification (e.g.: difficulties to find the right table).

Some of the experts raised concerns about the relevance of effects on the HPG as an endpoint as there is no quantified link to colony functioning. It was noted however that larval mortality has not been quantitatively linked to colony function level either.

The HPG-method should be validated, or at least more experience should be gained with the test protocol, for risk assessors to be able to evaluate and use it in the risk assessment.

Metabolites (difficult to determine whether toxophore is there)

The difficulty in performing the field studies for honeybees due to the statistical analysis required was acknowledged. Field tests were recognised to be even more difficult to conduct for bumblebees and solitary bees.

Q3: In which parts of the assessment did you use expert judgement (or weight-of-evidence)? Was the need associated to the guidance itself, to the availability of information in the reported studies, or to the lack of standardised protocols, valid study designs, etc? Please differentiate between lower tier and higher tier assessments.

It was overall concluded that expert judgement is needed for the risk assessment of bumblebees and solitary bees.

It was also mentioned that the relevance of off-field exposure to flowering weeds and adjacent crops in different periods of the year would need expert judgement.

Additional guidance is needed on when to use weight of evidence for the succeeding crop scenario to assess when the guttation is negligible.

For higher tiers, expert judgement is also required on how to evaluate studies and obviously on how to evaluate accumulative toxicity.

During the discussions, some study protocols were proposed for agreement at EU level also if not yet completely validated. This was the case for the following protocols:

- the 10-d chronic non-validated study (non OECD), the experts in support of this proposal explained that this method is already used in several laboratories and therefore the experience demonstrate that it is reliable enough.
- The acute tests for bumblebees, even though there is no OECD guideline yet.

- OECD acute larval test is now validated but GD uses only repeated dose; if applicants submit acute exposure test it requires expert judgement to decide how to use it.

For the chronic risk assessment to bumblebees and solitary bees, it was proposed to use honeybee data in accordance with the GD (page 226). However, this approach should be discussed and agreed at EU level.

3.2. Discussion on risk assessment and management dilemmas

Q1: Overall impression on clarity of risk assessment methodology (e.g. based on frequent differences of interpretation between group members). What suggestions do you have to improve the clarity of the methodology?

Some suggestions were proposed to restructure the guidance document to make it more user-friendly:

- The first tier methodology is generally clear. However, it was proposed that critical information available in the appendices could be more easily available if moved in the main assessment section.
- The risk assessment section was proposed to be a stand-alone section of the Guidance Document avoiding referral to appendices unless further explanation is sought.
- An additional chapter laying out the refinement options should be added, not only to clarify these options, but also to make reference to the relevant appendices easier.
- The EFSA Excel spreadsheet calculator tool was regarded as a promising aid, but needs to be validated. In the short term a "test" team for this tool with participants from Member States should be set up.
- Criteria need to be developed for performing an assessment of the accumulative toxicity including higher tier refinement.

Q2: Overall impression on data availability: what aspects of the GD could be introduced in the short-term?

<u>Honeybees</u>

Validated study protocols are available for acute oral and contact toxicity. It was agreed to assess chronic toxicity studies conducted according to the current methods or OECD draft guidelines but preference for agreed OECD protocols as more expert judgement was considered necessary to evaluate non-validated studies. OECD draft guideline for chronic toxicity test to larvae is available, though it differs somewhat from the test design described in the Guidance.

The HPG test was introduced in the Guidance Document to cover effects on the bee development stage. Currently no draft or validated guideline is available. It was proposed to set up a working group to discuss the outcome of this test and its use in the risk assessment. Doubts about the use of HPG as the most appropriate sub-lethal endpoint were raised.

As the HPG test is not available now, assessors need to be extra vigilant of sub-lethal effects seen in other studies, e.g. acute and chronic toxicity and larval study, in order to try to cover sub-lethal effects.

Refined contact exposure: Data are available to refine the contact exposure but deposition factors should be 'refined' with an increased generic dataset, rather than refining on a case-by-case (cfr refinement of Residue Unit Dose (RUD) in Guidance Document on Birds and Mammals). Refinement of the RUD would benefit from a harmonised approach e.g. to specify how many studies/data points are required. This residue refinement option should be validated with field studies that are already available and that have shown effects. Extrapolation for minor crops needs to be considered.

A question was raised whether it would also be possible to extrapolate to weeds in the treated field.
Data are available for a first tier assessment of the risk from pollen and nectar.

If an accumulative risk is identified, higher tier studies (including overwintering) will be needed (field studies). More guidance on this point is needed.

A large number of replicates are needed to fulfill the requirement to detect a 7% effect on colony size in field studies. It was questioned whether this is appropriate and feasible regarding both statistics and practical issues. Colony size is hugely variable naturally due to e.g. weather, disease and swarming. Beekeepers want field studies because they can potentially capture effects that are possibly missed in the first tier risk assessment.

Bumblebees

Acute oral and contact studies can be implemented now by using the draft ICPPR guideline. These studies would require expert judgment at the start, but are preferred above extrapolating from honeybee toxicity data.

Acute oral and contact test for bumble bees could be requested and used in the risk assessment to compare relative sensitivity vis-à-vis honey bees (in terms of a.s./mg bw) and to perform an acute risk assessment according to the Guidance Document. If acute endpoints are comparable, no safety factors should be applied, but different trigger values as suggested by EFSA.

For the 10-d adult tests for bumble bee it was suggested to use honeybee chronic data without a safety factor of 10 if acute tests indicate same toxicity (in terms of a.s./mg bw).

There are large differences between larval development of honey bees and bumble bees and therefore new test methods for bumblebee larvae need to be developed.

Bombus terrestris might not be most sensitive bumblebee species but the assessment factor should cover this variability. Data on the range of sensitivity of different bumble bee species would be useful to verify if this factor is sufficient.

The different exposure situation for bumblebees compared to honey bees needs to be investigated. The current schemes only cover the honeybee exposure routes, but exposure route is very different for other bees (e.g. via soil).

Solitary bees:

It was mentioned that acute oral and contact tests for Osmia can be requested and used in the risk assessment to compare relative sensitivity vis-à-vis honey bees (in terms of a.s./mg bw) and to do the acute risk assessment as proposed by the Guidance Document.

As for bumblebees it was suggested for the 10-d adult tests for Osmia to use honeybee chronic data without a safety factor of 10 if acute tests indicate same toxicity (in terms of a.s./mg bw).

There are large differences between larval development of honey bees and solitary bees and therefore new test methods for solitary bee larvae need to be developed.

Osmia cornuta and *Osmia bicornis* might not be most sensitive species of solitary bees. See discussion notes above for bumble bees on this point.

Q3: What are problematic parts in the EFSA guidance document when implemented in the EU regulatory process?

Concerns were raised about the ability to conclude due to the lack of data if the guidance is implemented immediately.
It was proposed to develop a road map for the implementation of the guidance based on the timeline of availability of ring tested/validated methodology.
The need to revise the uniform principles was also discussed.

Q4: Which suggestions do you have to increase the manageability/handling of this guidance for the national and EU registration processes (in a harmonised way)?

Also in this case, it was proposed to establish a 'roadmap' describing the implementation period and milestones to achieve along the way.

A harmonised approach for extrapolation and refinement options (more generic data) and options to reduce exposure should also be investigated (e.g. risk mitigation measures such as buffer zones).

A Working group needs to be established with risk assessors from Member States. EFSA should produce and finalize an user manual.

Results/outcomes of expert meetings need to be shared. It was also proposed to organise training for Member State and industry experts with the aim of disseminating information.

4. RISK MANAGERS BOG

Trigger values honeybees

5 trigger values are proposed linked to 5 endpoints (see page 88 + appendix M of EFSA GD):

a) Acute oral toxicity (ETR<0,2)

b) Acute contact toxicity (HQ < 42 or 85, depending on downwards/sidewards-upwards spray)

c) Chronic oral toxicity (ETR<0,03)

d) Development of Hypopharyngeal glands HPG (ETR<1) – sublethal effect

e) Larval toxicity (ETR<0,2)

The sublethal effects are relevant. But risk managers are not sure if the current indicator (HPG) is the best one. More scientific research should be carried out to confirm the scientific justification

The first 3 endpoints (a, b, c) are highly dependent on the level of *background mortality chosen*. EFSA selected the lowest mortality found on literature (5.3%) as a worst case approach.

On the subject of background mortality there was a lot of discussion, some MS think that the worst case approach should be re-discussed, by having options in several scenarios. On basis of those options one value should be chosen in a risk management decision.

Uniform principles. The trigger values for the acute risk to honeybees proposed in the GD are not in line with those in the Uniform principles. Furthermore, new trigger values beyond those in the Uniform principle are proposed. How can we deal with this?

A new set of UP must be developed to be in line with the new regulatory requirements. COM has to take the lead. What do we do meanwhile? What should be part of the UP (protection goals?) and what should be in the GD? Reference was made to the fact the new UP might be adopted via a delegated act and not via voting procedure in the SCoFCAH.

Evaluation is needed of the impact of the thresholds proposed in the GD. Could be done perhaps in a simpler way than a full impact assessment as understood by the COM.

Level of conservativeness of the trigger values proposed. Risk managers could consider increasing the selected value of background mortality rate (e. g. to choose the average value). This would lead to raising the acceptable ETRs for endpoints a, b and c (See EFSA GD page 171).

It is necessary to have options to be able to take risk management decisions. Some MS were asking for re-consideration of the first tier values.

It was generally felt that the protection goal (e.g. wild bee species) should be re-discussed.

Validated VS non-validated methods (honeybees)

Endpoints linked to thresholds c, d and e are based on non-validated test methods for which however proposed protocols exist (EFSA appendix O and draft OECD guideline). Those protocols relates to:

Chronic toxicity study with adult bee (oral) (endpoints= LC50 + NOEC for HPG)

Chronic honeybee larval toxicity (endpoint= NOEC larvae)

Do risk managers agree to use the newly proposed tests, although they have not been fully validated? To be noted that in the absence of these tests it won't be possible to calculate any endpoints for triggers c, d and e. As a consequence, chronic effects, sublethal effects and toxicity to larvae would not be covered by the risk assessment and by subsequent management decisions.

A screening procedure with non-validated tests was considered to be a tricky one. But it was also mentioned that it was better to have data to evaluate than having no data at all and that some of the methods and tests are being currently validated. It was suggested that a list of methods that are being developed and/or being expected to be validated by e.g. OECD or EPPO together with a timeline would be very helpful and that this list could be compiled by e.g. EFSA. They already have some of the methods listed in the GD. As a next step COM should be asked to link the methods listed into the data requirements document to make this transparent for all stakeholders.

Bumble bees and solitary bees

No validated test methods currently exist for bumble bees and solitary bees. However EFSA proposed protocols both for acute oral and contact toxicity (mainly readapted from the honeybees' protocol).

For the chronic toxicity and the larvae study EFSA proposed to use the honeybees' endpoints and to apply a safety factor of 10 to account for the uncertainty.

Additional safety factors for bumble bees and solitary bees are proposed in the GD when the endpoints from studies on honeybees are used (also from acute toxicity studies). The result is according to industry over-conservative. *Is the safety factors approach considered suitable? If so, which safety factors are considered appropriate?*

To be noted in this regards that also substances that could be considered as non-toxic to bees (LD50 >100 µg a.s./bee) fail the risk assessment for chronic toxicity to bumble bees and solitary bees according to the industry impact analysis. What are the reactions to this?

If the safety factors approach is not acceptable to risk managers, what the alternative could be? Is there a reasoning possible to accept a longer timeframe towards an assessment for bumble bees and solitary bees? Could we develop a roadmap leading to a practicable and valid assessment?

We need to have more research in the field of solitary bees and bumble bees/wild bees. There is certainly a gap in knowledge. However some lab methods can be adapted and used in the meantime for screening differences in sensitivity

We also need a discussion on the protection goals. This has two components: - the population should be protected to a certain level, but also the ecological function. Separate those two issues

Field studies

The most important issue that will affect higher tier risk assessment is the specific protection goal (SPG) on an effect on colony size not greater than 7%. Some experts noted that measuring this small difference might be extremely difficult.

7% corresponds to a **negligible** effect and it means that foragers mortality should not be increased compared with controls by a factor of 1.5 for six days or by a factor of 2 for three days or a factor of 3 for two days. This protection goal was decided by risk managers when consulted on the draft GD in 2012.

Do risk managers believe that this protection goal should be reconsidered?

Some MS felt that the 7% was too low. Based on expert judgment this figure should be higher. It was also argued that currently a better model is available to estimate the 'normal'/realistic development and mortality of a colony. Many MS were thinking that the 7% should be re-visited as value for negligible effect.

Risk manager options

Harmonisation of risk mitigation methods is an important issue here. E.g. the labeling of products.

Additional risk mitigation methods should be assessed by risk assessors or EFSA GD in order to give more options, so that risk managers can take decisions based on the options given by experts.

5. CONCLUSIONS

It was concluded that a full and immediate implementation is not possible at this stage. A roadmap for the implementation of the Guidance Document and further development of higher tier studies will be drafted by the Commission to be discussed in a Working Group with experts from Member States and EFSA. EFSA agreed to restructure the Guidance Document to make it more user-friendly. Training for Member State risk assessors on how to use the Guidance Document and the associated calculator will be arranged in co-operation with EFSA. A review of the protection goal and trigger values was considered necessary, in particular for bumblebees and solitary bees. Finally, the Commission was asked to reflect on the necessity to amend the Uniform Principles (Regulation (EU) No 546/2011) regarding hazard quotients and other acceptability values, and the data requirements to further clarify which studies will be required.

6. ANNEXES

i) Agenda

ii) Reports from breakout groups

iii) EFSA presentations