

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 agenda containing additional information for the rapporteurs.

Tuesday 10 December Arrival of participants
18:30-19:30 Registration

opm 10.2.g: ik heb gisterenavond aan COM gevraagd deze meeting (locatie/tijd etc te regelen. Hoop snel antwoord te krijgen! Bij meeting ook de EFSA betrekken) Meeting of RAPs and chairs : 19.30 – 21.00? It is probably not feasible to meet earlier than this, not even in a teleconference.

Wednesday 11 December 08:30 Registration and coffee

Wednesday, 11 December **PLENARY SESSION**

Chair: COM

09:00 Opening, Welcome (COM)
09.10 Introduction to workshop (objective and structure) (COM)
09 20 Introduction to the Guidance Document, comments received, EFSA's pass/fail rate analysis (10.2.e)
10 00 Implementation of the first and second tier risk assessment (10.2.e)
10.40 Coffee break and arrangement in break-out groups (BOGs); each with a chair (COM) and a rapporteur
11 10 Questions and answers as regards EFSA's presentations

This will probably happen also in a plenary session, but if not, there will be an EFSA representative in every BOG

Wednesday, 11 December **WORKING GROUP SESSIONS**

Working in four mixed risk manager-risk assessor BOGs in parallel on eight different example cases. Per BOG two cases will be discussed. Each group will be further divided in two sub groups. Those will discuss on 1) honeybees or 2) bumblebees and solitary bees.

A break-out group will contain 10-15 people. These will be divided in two subgroups. For the first case, one subgroup will work on honeybees, the other on other bees. For the second case, this will be reversed so that everyone works on all bee groups.
For the first case, both RA and RM will be present during the whole session. For the second case, the RM will only be present at the wrap-up (wrap-up will therefore take longer for the second case).

Time per case:

- 1) 3.05 h
- 2) 3.45 h

It is essential that the RAPs are thoroughly prepared and know their two cases. They should have a filled-in version of both the spreadsheet and the reporting format on their laptops. Also, they should already have ideas about both sets of questions.

Furthermore, RAPs should stimulate solution-forming/finding to identified obstacles/problems.

The RAPs are responsible for providing the homework package of their two cases. See separate document – RAP info on homework cases.

On day 1 of the workshop, the goal is to answer the first set of questions:

- 1) Which parts of the guidance were clear enough and which parts of the guidance caused difficulties due to insufficient clarity or different interpretations?
- 2) Which parts of the guidance were easily followed and which parts of the guidance caused difficulties due to the complexity of the guidance requirements?
- 3) In which parts of the assessment did you use expert judgment (or weight-of-evidence)? Was this necessary as per the guidance itself, as a result of lack of information in the reported studies, or to the lack of standardized protocols? Please differentiate between lower tier and higher tier assessments.

This goal is achieved by:

- a) filling in the spreadsheet = working through the risk assessment scheme; in small groups (2-3 people), on participant's own laptops. RAP and chair move between these subgroups to answer questions and steer the process. The process starts with the 'empty' spreadsheet which was given in the homework package (Note: to be discussed - how empty?; see separate document). If finding the input parameters takes too long, RAPs can provide them after e.g. 15-30 min.
- b) After ca. 1.5 h: start filling in the reporting format (smilies/frownies) in subgroup, on laptop of rapporteur; then formulate answers to questions, in whole BOG, on laptop of rapporteur (shown on screen).

The reporting format will be presented to the whole workshop in the 9.00 session of the second day.

The focus should be on the first set of questions. Comments that already relate to the second set of questions can be put on a separate sheet of paper, for discussion the following day (Day 2).

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| 11.40 | Start discussion first case |
| 13.00 | Lunch |
| 14.00 | Further discussion first case |
| 15.30 | Coffee break |
| 16.00 | Wrap up first case |
| 16.15 | Start discussion second case, risk managers in separate BOG |

- 18.00 Snack
- 18.15 Further discussion second case
- 19.30 Wrap up second case, risk managers join BOG
- 20.15 Cocktail
- 20.30 Dinner
- 22.30-23.00 Meeting chairs and rapporteurs

In this meeting, the results of the day are discussed and the 9.00 session of the next day is prepared.

Thursday, 12 December
PLENARY SESSION

Chair: COM

- 08.45 Coffee
- 09.00 BOG-chairs present results from their BOGs based on template with smileys/frownies plus answers to first set of questions

The results of the cases and the answers to the first set of questions (as recorded by the RAPs) are presented by the chairs of the BOGs in a plenary session.

- 10.30 Coffee break

Thursday ,12 December
WORKING GROUP SESSIONS

- 11.00 Discussion of risk assessment and management dilemmas in four mixed risk manager-risk assessor subgroups (the four BOGs that started on 11 December), listing of problematic areas in EFSA Guidance document and proposing solutions for practical and harmonized use in the regulation; reporting to be based on second set of questions.

The BOGs (same as previous day; both RA and RM included) meet to answer the second set of questions (whole BOG together, RAP records final answers of the BOG):

- 1) 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 ?
- 2) Overall impression on data availability: what aspects of the GD could be introduced in the short-term?
- 3) What are the most problematic sections of the EFSA guidance document, from the perspective of implementation in the EU regulatory process ?
- 4) Ik heb gisteren gekozen voor het alternatief in het programma dat naar COM is gestuurd. 10.2.e correctie van de tijverdeling tussen beide casussen heb ik meteen ook aan COM gestuurd; hoop

datze die versie pakken om te versturen. Ik heb nog niets langs zien komen!!!! Which proposals for solutions do you have for practical and harmonized use of the EFSA guidance in the regulation ?

12.30 Lunch
Chairs and rapporteurs will meet during lunch under chairmanship of 10.2.e to analyse proposals for solutions and to produce a list of the most promising proposals

Chairs and RAPs will have lunch in a separate room and prepare for the 13.30 session. One or two of the RAPs will prepare the slides.

Thursday ,12 December
PLENARY SESSION

Chair: COM

13.30 Outcome lunch meeting will be presented by chair (10.2.e) as basis for a discussion on proposals for solutions for practical and harmonized use of GD

15.30 Coffee break
Chair (10.2.e) supported by rapporteurs prepares proposals for conclusions and options for implementation of the guidance in the EU regulatory process

Chair and RAPs (*and possibly also BOG chairs*) will meet in a separate room. One or two of the RAPs will prepare slides for the 16.00 session.

16.00 Drafting of conclusions on practical solutions; recommendations and, if necessary, proposals for further activities of COM and EFSA

This will be presented by the chair.

16.30 Closing