

# Stakeholder and MS consultation on the preliminary considerations and planned methods for the revision of Tier 1 risk assessment schemes of EFSA's 2013 guidance document

Fields marked with \* are mandatory.

## General considerations

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Dear Stakeholders, Dear Member State contact points,

Welcome to the 3rd consultation related to the EFSA bee Guidance Document!

This consultation is about the preliminary considerations and planned methods for the revision of the Tier 1 risk assessment schemes of the guidance document.

The survey consist of only two parts. In the first part you can raise specific comments on particular sections of the document and in the second part you can add some general comments.

*By accepting the terms, I confirm that I have read and understood the context as described above. I confirm that the comments below originate from me or from the organisation I am representing and I confirm that I did not delegate the commenting to a third person.*

I accept your Terms

## Identification of the commenter

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\* Please select

- I am a MS representative
- I am a stakeholder as identified by EFSA for this review ([Report-SH](#))

\* Please indicate your country:

- |                                      |                               |                                       |
|--------------------------------------|-------------------------------|---------------------------------------|
| <input type="radio"/> Austria        | <input type="radio"/> Germany | <input type="radio"/> Poland          |
| <input type="radio"/> Belgium        | <input type="radio"/> Greece  | <input type="radio"/> Portugal        |
| <input type="radio"/> Bulgaria       | <input type="radio"/> Hungary | <input type="radio"/> Romania         |
| <input type="radio"/> Croatia        | <input type="radio"/> Ireland | <input type="radio"/> Slovak Republic |
| <input type="radio"/> Cyprus         | <input type="radio"/> Italy   | <input type="radio"/> Slovenia        |
| <input type="radio"/> Czech Republic | <input type="radio"/> Latvia  | <input type="radio"/> Spain           |



## PART 2: Outline of the risk assessment process

*4000 character(s) maximum*

We note that honey dew is not listed as a potential exposure scenario (as it is not a scenario in EFSA, 2013). We consider this a relevant exposure route.

### 3.3.1. Exposure routes and scenarios

*4000 character(s) maximum*

The exposure routes currently considered seem mainly focused on honey bees, whereas other (particularly wild/solitary) bee species may have other exposure routes which are more important/relevant than those currently considered. It may be difficult in the scope of this update to fully delineate other exposure routes, but it should at least be addressed whether they are expected to be covered by the exposure routes used, or a combination of these assessments with the RA for other NTAs.

#### 3.3.2.1. Dietary model

*4000 character(s) maximum*

MAFbf: How likely is it that and to what degree would residues build up in nectar and pollen from application before flowering? If it is assumed that all substances can both trans-locate to and build up in pollen and nectar when applied before flowering, is that quite a conservative assumption? In which case, what is the impact on the assessment overall of this assumption?

#### 4.1.1. Succeeding crop scenario

*4000 character(s) maximum*

We agree with the need to re-evaluate the triggers of 2 and 5 days, as they seem very conservative. This is especially true in cases of following year succeeding crops.

We agree with the need to further outline and determine the appropriateness of the use of the PEC<sub>pore</sub> water to determine succeeding crop residues in pollen and nectar.

#### 4.1.2. Weeds in field scenario

*4000 character(s) maximum*

#### 4.1.2.1

It is not clear what impact the percentage of total ground coverage of weeds has on the likelihood of bees foraging in the fields, as opposed to, for example, the number of flowering weeds present or the attractiveness of the kinds of weeds present. Also, it is not clear what effect good agricultural practice has on this. National-specific normal agricultural practices and national specific risk mitigation related to this should also be mentioned/considered.

#### 4.1.2.4

We generally agree with the identified uncertainties in the report of Last, 2019, and also with the assumptions /update made by EFSA in the re-assessment of the data.

#### 4.1.2.6

We agree that the weeds in the crop scenario is relevant in permanent crops regardless of growth stage (of the crop).

#### 4.1.3. Pre-flowering factor

*4000 character(s) maximum*

We agree with the proposed approach to determine a PFF for modification of the SVs for pre-flowering uses. We note that it was implied, though not explicitly stated, that the factor may be temporally dependent (depending upon the likely time between application and flowering). We recommend that the reasoning be as explicit as possible to allow assessors to understand these and modify where necessary in higher tiers or depending upon the GAP.

#### 4.1.5. Landscape dilution factor

*4000 character(s) maximum*

Due to major differences in land use between MS, it might be very difficult to determine a generic LDF < 1 for the Tier 1 assessment. In a higher tier scenario, where the assessment becomes more focused/specific, land use and studies such as mentioned in a - c might be submitted as a refinement. In that case, clear guidance should be provided on how to perform and evaluate such studies.

#### 4.1.6. Water consumption

*4000 character(s) maximum*

We agree with the assumptions of the WG concerning question 1.1.

#### 4.2.1. Inter-species toxicity endpoint difference

*4000 character(s) maximum*

We recommend that special consideration be given to understanding the uncertainties inherent to the toxicity data and explaining how these are addressed in the risk assessment. This includes, of course, extrapolation between species, but also between laboratory and field, and other inherent uncertainties (exposure duration and frequency, etc.).

#### 4.2.2. Extrapolation factor beyond the tested rates

*4000 character(s) maximum*

We support the methodology proposed by the WG for the extrapolation factors.

#### 4.2.3. Suitability of the OECD 239 Guidance Document

*4000 character(s) maximum*

We agree with the preliminary conclusion regarding OECD 239 and the (lack of) exposure of larvae during the first 2 days.

#### 5.1. Methods to assess crop attractiveness

*5000 character(s) maximum*

We would consider exposure via honey dew to be relevant, and that crops for which aphid infestation/honey dew production is relevant might be considered.

#### 5.2. Methods to estimate food consumption

*5000 character(s) maximum*

Q4: Daily duration of foraging. If the daily duration of foraging is influenced by sugar content in crops, will this parameter be assessed per crop or a generic value will be derived?

#### 5.3. Methods to estimate crop-specific sugar content in nectar

*5000 character(s) maximum*

It would be good if electronic copies of PhD theses and other relevant material are requested from professional network in cases where they cannot be retrieved online. Why will PhD theses in other languages than English be dismissed? This may create a bias.

## General comments

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You can post here any general comment regarding the plans and the outcomes presented in the document:

*5000 character(s) maximum*

A number of uncertainties and assumptions are mentioned, but it is not mentioned how these will be formally addressed in the update. We would assume that these will be collected and collated in a rigorous manner to facilitate a formal reporting of the uncertainties and their effect on the RA at the end of the process.

Please insert here the references of publications that support your earlier comments by issue:

	Reference or link
PART 3 - Problem formulation	
Succeeding crop	
Weeds	
PFF	
Protein	
LDF	
Water	
Inter species factor	
Extrapolation beyond tested range	
OECD 239 - jelly	
Attractiveness	
Food consumption	
Sugar content	
Residue levels & TWA	
fdep & Ef	
Any other	

**Thank you for your contribution!**



**Contact**

