







Minutes pre-submission meeting GRG-AGG Literature search and LRR

Date: Wednesday December 11th, 2019

Time:13.00 – 15.00 hLocation:Teleconference

1. Opening

On behalf of Assessment Group of Glyphosate (AGG), the chair of the meeting welcomes all participants. The chair of the Glyphosate Renewal Group (GRG) thanks the AGG for organizing this meeting (The Glyphosate Task Force 2 decided to change its name in Glyphosate Renewal Group. This name should mark better the difference between the Taskforce glyphosate from the last renewal and the current renewal.)

All other participants are introduced by a tour de table.

2. Aim of the meeting and disclaimer

This pre-submission meeting (PSM) is intended to discuss issues and questions raised by the applicant in preparing their dossier in the field of the literature search.

The meeting is held to assist the applicant in preparing their dossier and is not legally binding. The advice given does not bind the Member States, EFSA or the European Commission and should not be seen to create any expectations on the part of the applicant concerned.

The assistance and advice is solely based on the information made available by the applicant for the meeting. It is the responsibility of the applicant to present a complete picture of the data to be discussed. This does not preclude any other points which may arise after dossier submission.

The minutes of this meeting will be finalized after the consent of all parties present.

3. General literature search and literature review report (LRR)

Reference is made to the GRG presentation 'General literature search and literature review report (LRR)' (attachment 1).

Slide 2:

AGG made GRG aware of an Appendix to the EFSA GD 2092/2011¹.

Slide 4:

AGG reminds GRG that in the EFSA peer review process, an updated literature search may be requested reflecting the literature published between Dec 2019 and June 2020.

Slide 6:

AGG encourages GRG to submit a list of all non-relevant articles and the justification for their exclusion (so called Table 4 in presentation).

AGG advises GRG to include all relevance criteria and reliability criteria in the literature review report in a tabled format.

¹









Slide 7:

AGG asks GRG to explain what happened to the 3561 articles missing in the overview. GRG refers to slide 13 where it is explained that these 3561 references are duplicates, efficacy studies and other studies. AGG advises GRG also to include these studies in 'Table 4' so during assessment AGG can check whether it agrees with the choices made, or not. GRG can agree to that and will proceed accordingly.

Slide 15:

On the slide example relevance criteria are given. AGG acknowledges that these are example criteria, however, AGG made the following remarks: AGG advises GRG that <u>all</u> routes of exposure, and not only the most obvious ones, are of importance to the dossier..

Reports on deliberate poisoning (e.g. suicide) are to be submitted as part of the dossier (section 5.9 of Regulation (EU) No 283/2013) and therefore cannot be excluded from the literature search.

Slide 16 and 17:

GRG explains that the relevance criteria for the detailed assessment are a further elaboration of the criteria in slide 15. So, the slide 15 can be seen as a subset of slides 16 and 17. AGG emphasizes that a clear breakdown and sufficient explanations on why specific literature items are in- or excluded is important for the assessment of the search.

AGG emphasizes again that all relevance criteria and reliability criteria should be listed in the literature review report.

AGG emphasized that if data from outside EU are relevant for EU conditions, they should be included in the literature review report.

Slides 20, 22-25

All metabolites of glyphosate are to be included in the literature search (e.g., including HMPA for ecotox).