Minutes pre-submission meeting GTF2-AGG
Residues, Toxicology

Date:	Friday, October 18th, 2019
Time:	10.00 – 15.00 h

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1. **Opening**
   On behalf of Assessment Group on Glyphosate (AGG), the chair of the meeting welcomes all participants. The chair of the Regulatory Working Group of the Glyphosate Taskforce 2 (GTF2) thanks the AGG for organizing this meeting. 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 Residues and Mammalian Toxicology.
   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. **Residues**
   Reference is made to the GTF2 presentation 'Glyphosate EU Annex I Renewal – Residues (attachment 1).

   Slide 15 (residue analytical methods – extraction efficiency):
   AGG agrees with GTF2 that the extraction efficiency of the new methods is considered to be sufficiently covered by existing data.

   Slide 36 (plant metabolism studies – conclusion for genetically modified crops):
   GTF2 stresses that it is not foreseen that genetically modified crops will be defended for EU. Slide is shown for the possibility to set import tolerances.

   Slide 56 (field residue trials – top fruit plantations):
   AGG will evaluate the extrapolations by expert judgement. AGG will follow the principles, approaches and recommendations of the MRL review of glyphosate.

   Slide 58 (fiels residue trials – pre-sowing and pre-planting use in annual crops):
   AGG will evaluate the extrapolations according to the current guidelines, which can provide cases for expert judgement. AGG will follow the principles, approaches and recommendations of the MRL review of glyphosate.

   Slide 70 (processing studies – nature of residues):
   Proposed study design seems acceptable but needs to be evaluated before conclusions can be drawn.
   AGG stresses the importance that the method is suitable for analysis of the metabolite AMPA (sufficiently validated).

Slide 71 (processing studies – magnitude of residues):
AGG recommends to submit the studies on the magnitude of residues in processed commodities as supplementary data.

Slide 73 (residues in rotational crops):
AGG can follow the approach to address the possible uptake of parent glyphosate and AMPA residues in rotational crops with trials for pre-sowing, pre-planting, or pre-emergence uses of the active substance. However, the outcome of the evaluation will strongly depend on the fate of the metabolite AMPA in soil (PECsoil).
Studies from outside EU cannot be accepted for evaluation, unless it is clearly demonstrated that they are representative for EU-uses, EU soils and EU-climate.

Slide 78 (residues in honey – study results):
The study design for residues in honey seems acceptable.

Slide 79 (residues in honey – monitoring data):
In case the honey MRL would be based on monitoring data, the monitoring data need to come from an official monitoring program.
AGG can however take into account field data.

4. Mammalian Toxicology

Reference is made to the GTF2 presentation 'Glyphosate EU Annex I Renewal – Toxicology (attachment 2).

Slide 11 (genotoxic potential of formulations):
AGG considers that sufficient information to address the data requirements for the active substance and the representative formulation(s) is required. Therefore, the genotoxicity studies with the representative formulation(s) should be submitted as well as all public literature information that is considered relevant and reliable on the active substance, the representative formulations. Genotoxicity studies with other formulations should be submitted on Member State level.
AGG will align with the EFSA statement on mixtures (Genotoxicity assessment of chemical mixtures, adopted 22 November 2018, doi: 10.2903/j.efsa.2019.5519). However, more discussion will be needed on how to deal with this EFSA recommendation on mixtures.

Slide 12 (genotoxicity studies for glyphosate based formulations (GBFs) and formulation components):
Refer to answer for slide 11.

Slide 17 (endocrine disruption – preparation of Appendix E):
Refer to minutes of pre-submission meeting AGG-GTF2 dated 17 October 2019.

Slide 29 (rabbit development tox studies):
AGG comments that these type of questions require an in-depth analysis and interpretation of the data package for the active substance and can thus not be addressed at this stage of the process. The purpose of the review is to re-assess all data available and also to consider an updated literature search, then decide whether or not conclusions from the previous assessment should remain or need to be changed.

Slide 30 (endpoint selections):

AGG comments that these type of questions require an in-depth analysis and interpretation of the data package for the active substance and can thus not be addressed at this stage of the process. The purpose of the review is to re-assess all data available and also to consider an updated literature search, then decide whether or not conclusions from the previous assessment should remain or need to be changed.

Slide 41 (phototoxicity and photomutagenicity (photoreactivity)):
Provided that existing data is confirmed relevant and reliable and results indicate that the criteria for phototoxicity and photoreactivity are not met, further testing is not needed.

Slide 42 (ANSES – study plan on the carcinogenic potential of glyphosate):
AGG indicates that it is unsure how the studies on the carcinogenic potential of glyphosate will be handled in the course of the renewal evaluation. The call is still ongoing. It is unknown yet if there will be a CRO to perform the studies and when the studies will be finalised. If available in time, the studies can be submitted in the peer review process.

In the light of the substantial use of glyphosate AGG advises GTF2 to thoroughly evaluate all public literature, although not conducted according to GLP, and incorporate these results in the dossier. In light of the public concern, there is a need to evaluate these date on the level of active substance assessment. In this light, the IARC report is also to be taken into account.