Minutes of the pre-submission meeting GTF2-AGG 27 September 2019

Date:	Friday, September 27th, 2019
Time:	10.00 – 16.00 h
Location:	DG Santé, Rue Foissart 101, Bruxelles

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1. **Opening**

   On behalf of Assessment Group of 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 presubmission meeting (PSM) is intended to discuss issues raised by the applicant and is not legally binding. The meeting is held to assist the applicant in preparing the dossier. 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. It is the intention to have an open discussion. During this PSM procedural issues, timelines, GAP's, public literature etc. will be discussed. For issues which require technical support, expert meetings are organized on October 17 and 18, 2019.
   - GTF2 will compile presentations for the expert meetings, which will be distributed 2 weeks in advance (October 2nd). The AGG agrees to this proposal.

3. **Minutes pre-pre-submission, for adoption**

   The minutes of the pre-PSM have been circulated. They are adopted with all people present. The minutes will be published on the public AGG-website hosted by the Commission. Personal information will be removed, according to Regulation (EC) n°1049/2001.

4. **Timelines**

   GTF2 and the AGG agree that the application must be sent in on December 15th at the latest. The experts and project managers are informed that the check must be done during the Christmas period.

5. **Issues, based on the presentation (see Procedural PSM Slides GTF2 final)**

   - Membership - 2019 GFT2: there is still discussion with 4 or 5 other potential members, the overview (slide 6) does not include the final list. In theory these members can bring in a new set of sources of the active which may already be registered but are not part of the GTF2 set yet. An updated list will be presented by the end in the application. GTF2 is not in a position to exclude new applicants at a later point in time. In case GTF2 becomes aware of a second application it will discuss with other applicants if they want to join the taskforce. GTF2 asks the AGG to forward the contact details of a new applicant to allow contact to be made.
   - Contact points (slide 7): AGG agree to the proposal with the exception of the communication between AGG and individual TF members.
     The AGG has one contact point, which will be the chairperson until further notice. Within the near future there will be a central email address for communication. Chairmanship will change every half year.

Ctgb chairs the AGG until 31st December 2019. Anses will be chair as from January 1st until July 1st 2020.
GTF2: for organisational questions the chair of the GTF2 regulatory group is the contact point. For all other matters, it will be the consultant Knoell.

- Work sharing within AGG (slide 8/9) –format of submission:
  For KEMI and Ctgb two dossiers in Caddy format and for Anses and NÉBIH one dossier in Caddy format are requested. A paper version is not necessary.
  There will be work sharing between the AGG members but they operate as one entity including signing and sending the dossier to EFSA. There is no RMS or co-RMS, hence for GTF2 no further information about work sharing is necessary. There will be more detailed information about the communication during the assessment process.
- AGG confirms that the AIR 5 application document should be in line with the mentioned regulations (slide 11).
- Representative formulation (slide 12): AGG asks the GTF2 if they thought about representative uses taking into account the specific provisions as stated in Commission implementing regulation (EU) 2017/2324 (e.g., protection of groundwater, operators and amateur use, risk to biodiversity). GTF2 will come back on this in the expert PSMs for a more detailed discussion.
- New studies (slide 13): these have to be listed exactly according to the format in the EFSA administrative guidance document (27 March 2019) which is applicable at the time of the application.
- Pre-check (slide 14): AGG replies to GTF2 that a pre-check is not part of the process because the regulation does not foresee a pre-check. After the deadline for final submission of the application by 15 December 2019 there is 1 month for the AGG to check and if needed, 14 days for correction of the application by GTF2.
- Guidance documents (slide 16): AGG confirms that only guidance is applied that entered into force at the time of the submission of the dossier unless new guidances or regulations come into force which will be also applicable for ongoing applications.
- **Topic for expert meetings October 17th -18th, 2019**: list of guidance documents and data requirements for the renewal dossier. AGG inquires after how GTF2 will address the data requirements and open points listed in the EFSA conclusion and/or in the renewal regulation for glyphosate, for instance concerning risks for biodiversity. This will be discussed during the expert meeting.
- Studies and data access (slide 17): AGG informs that as assessors they are obliged to take all information, including JMPR studies but also including data protected by IP or data protection into consideration that point to adverse effects. Art. 56 of the regulation is the basis for this and since glyphosate is already on the market, this article applies also for the renewal. However AGG cannot inform GTF2 on data GTF2 has no access to.
- Specifications at EU level (slide 18): AGG asks for a summary of all specification checks that are performed of all sources. This can be in the form of an additional document provided by Knoell.
- Reference specifications (slide 19): AGG informs that also the EU rules apply, even if an FAO specification exists for glyphosate.
- Fundamental data set (slide 21/23): RAR list of studies. The AGG as assessors will decide about the relevancy of studies, therefore they need robust OECD summaries of all studies available, not only the recent ones or those considered as relevant by the GTF2.[1]
- Data packages (slide 22): AGG states that they have to evaluate all information on glyphosate that is available whether relevant or not. All summaries have to be presented in the robust OECD format.
- Pre-check meetings (slide 24): AGG informs that a pre-check is not part of the process. AGG informs that for the admissibility check according to Art 8 of Regulation (EU) No 844/2012 the

[1] Post meeting note: AGG summarized its advice in the document "ADVICE TO GTF2: HOW TO SUMMARISE STUDIES IN DOSSIERS FROM 1998 AND 2012 IN THE DOSSIER TO BE SUBMITTED JUNE 2020" (Appendix 1)

"Stop the clock" period is 14 days instead of 30 days as mentioned in the slide. AGG will meet the deadlines as well as EFSA.

- Interaction for clarification between AGG and GTF2 will be organized in a transparent way.
- The timelines may vary pending the on-going discussion of the amendment of Reg 844/2012.
- GTF2 will present the dossier June 2020.
- Literature review report preparation (slide 26): AGG agrees with the proposal.
- Literature search (slide 28/29): this has to be done for the last 10 years before the date of dossier submission, June 15th 2020, meaning that GTF2 will have to go back to June 2010 and cover the public literature until December 2019 (i.e. until six months before submission)[2].The selection of relevant studies and public literature has to be a clear and transparent process performed according to the EFSA guidance. GTF2 should provide AGG with a clear breakdown of the hits in the literature search according to relevance. Clearly legal or socioeconomic publications are not relevant, but for other categories (e.g., efficacy, analytical methods) a clear reasoning should be followed.[3]
- Harmonized classification and labelling (slide 32): AGG will prepare a CLH proposal because since the last classification, literature has expanded also to issues relevant for the classification. The CLH-dossier will be part of the assessment report of AGG, but it is to ECHA to decide whether a new classification process, including public consultation and RAC-opinion, is warranted. As it comes to AGG evaluation, no effect on the timeline is expected as the CLH part of the dossier will be provided in the joint template for DAR and CLH report.
- GTF2 is advised to present the data as described in Appendix F to the EFSA administrative guidance document (27 March 2019) and encouraged to present in detail a comparison with the classification criteria. AGG will use the combined format for RAR and CLH so there will be no extra administrative burden.
- GAP table (slide 34): AGG notes the focusing of the GTF2 slides on agricultural uses only, whereas part of the discussion during the previous renewal touched upon non-agricultural (hard surface) uses.
- Transparency, General Food Law (GFL) (slide 39): EFSA informs that glyphosate does not fall under the rules of the GFL, which will only apply as of mid 2021 and therefore there is no legal basis to help or organize the notification of studies by GTF2 for public consultation.
  GTF2 informed they will have a special website from December 1st, 2019 for publication of all submitted studies required and agreed by the authorities. EFSA replies that they will keep their own role and mandate according to the legislative framework in place.

  AGG states it is important to divide the issue in two: the legal requirements for all parties (GTF2, AGG and EFSA) are binding. Nevertheless, on all other aspects cooperation and an open communication is important to aim for a transparent process. GTF2 is willing to reflect with EFSA on the possibilities of public consultation for this special case only.
  AGG asks GTF2 to keep them informed of its plans.
- Disclosure of minutes, emails etc. AGG states that this is not only an issue of transparency but also of legal constraints for the governmental bodies involved. All members have their own disclosure rules to which they are bound. Therefore it is important that both AGG and GTF2 have the possibility to react on proposed publications and, when necessary, to inform each other. Personal information will be removed, according to Regulation (EC) n°1049/2001.
- GTF2 agrees to keep each other informed.

6. AOB

[2] This point was discussed in a later teleconference GTF2/AGG and it was concluded that the search should start at June 2010 and end Dec 2019 for the dossier, and that the updated search from January 2020 to June 2020 would need to be submitted afterwards, during peer review.

[3] Post meeting note: AGG summarized its advice in the document "ADVICE TO GTF2: HOW TO PRESENT THE LITERATURE SEARCH IN THE DOSSIER TO BE SUBMITTED JUNE 2020" (Appendix 1).

- Distribution of overall costs: each AGG member will send their fee information to Knoell. There will be no separate contract between GTF2 and AGG, the regular provisions will suffice.
- Data access to studies relevant for the GAT technology for glyphosate resistant crops: GTF2 is currently negotiating access to these data but outcome is open. GTF2 stated that this technology is not relevant for the glyphosate uses in EU, but evaluation of the data could be relevant for import tolerances. (Reg 844/2012 article 7, par. 1i)
  Topic for PSM 17-18 October.
- If necessary an extra technical PSM about literature search can be organized.

7. Wrap up

- The individual AGG members operate as one entity and AGG will ensure that the necessary communication with GTF2 will be adequate for all parties involved.
- The regulation is binding, including the timelines, so there will be no pre-check or a change in the date of application.
- Applicable regulations, guidances: all guidances into force at the date of submission of the dossier will be implemented. New guidances will be implemented only if the Commission decides that these will be binding also for ongoing applications.
- Data sharing etc. all confidentiality rules will be followed, however if there is knowledge of adverse effects, AGG will call in Article 56. If AGG knows of studies beneficial for the dossier which are protected however they cannot and will not share this information with GTF2.
- Reference specifications: AGG informs that also the EU rules apply, even if an FAO specification exists for glyphosate.
- Volume of studies: AGG will come back on their position. Concerning the redundant studies: this has to be discussed. In the expert meeting it will be discussed how to tackle the amount of studies and how to analyse the information. After the expert meeting a final decision will be taken how to do that; this refers also to the need for robust OECD summaries for all studies in the dossier.
- Valid or reliable studies: AGG needs more information than a table. A clear reasoning must be provided. Will be discussed later on.
  (see note 1 on page 3)
- Literature search: from June 2010 onwards. AGG will come back later on the request of GTF2 about the breakdown of number of publications and studies. If necessary a specialised meeting will be organized to discuss this topic. (see note 3 on page 3)
- Transparency: AGG endorses the decision of GTF2 to follow the coming amendments of the General Food Law, however this cannot be executed by AGG and EFSA since these amendments are not yet in the mandate. AGG requests to be informed by the GTF2 in advance about documents to be published. Names must be left out.
- GAP: GTF2 should consider having a GAP covering the worst case uses, for example the use on hard surfaces and risk of run off.
- Because of the importance GTF2 will give information about the status of members of the GTF2 and the sources they will use.

The chair thanks all attendees for their participation.

Appendix 1:

ASSESSMENT GROUP ON GLYPHOSATE (AGG)

October 2019

ADVICE TO GTF2:
HOW TO SUMMARISE STUDIES IN DOSSIERS FROM 1998 AND 2012
IN THE DOSSIER TO BE SUBMITTED JUNE 2020

- This paper is meant to clarify how studies from the old dossiers should be presented in the dossier in June 2020.
- "Old dossiers" refers to the glyphosate dossiers from 1998 and 2012, respectively, including the additional studies that were submitted during the review processes up to the final decisions in 2001 and 2017, respectively.
- This advice refers to studies owned by the Industry and to studies from the open literature, presented in the old dossiers.

1. Studies that previously were considered as relevant and reliable:

Section 3.16 of the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances (March, 2019, doi: 10.2903/sp.efsa.2019.EN-1612) says:

> *"The study summaries (for both laboratory and higher tier studies) reviewed in the original DAR and/or Addenda, should be included in respective MCA and MCP sections of the dossier, and should be updated in order to have a similar level of information as in the summaries of the new studies submitted for the renewal procedure (i.e. the tables of biological findings, tables of analytical findings and validity criteria should be added). The applicant should ensure that any corrections and comments made to the original study summaries in the previous DAR/RAR and in the available EFSA conclusion are reflected in the updated study summaries of old studies. Therefore, the applicant should provide an assessment of old studies against current guidelines and requirements submitted through updated and robust OECD study summaries (submitted in the original dossier) that are self-standing, sufficiently detailed and transparent, as part of the supplementary summary dossier."*

In March 2019, the Standing Committee on Plants, Animals, Food and Feed (Section – pesticides legislation) agreed that the EFSA Administrative guidance should apply for dossiers submitted from 1 October 2019 (see document SANTE-10914-2019 rev. 0, 22 March 2019. Therefore, the Assessment Group on Glyphosate (AGG) strongly recommends the GTF2 to follow the quoted guidance for the dossier in June 2020.

2. Studies that are not considered as relevant/reliable for the dossier 2020:

This section refers to studies that were not considered as relevant/reliable by the RMS in the old DAR or RAR or by the peer review of these documents, respectively.

The studies should be presented in the dossier June 2020 and summarised with at least the following information:

Report:	
Title:	
Laboratory report/project number (Doc. No.)	
Guidelines:	
GLP:	
Previous submission:	*refer to dossier 1998 or 2012, as relevant*
Short description of study design and observations:	*test substance and test system (e.g., animal species and strain, study duration, number of soils etc.) should always be stated*
Short description of results:	*this should include key findings such as adverse effects observed (in particular for repeated dose toxicology studies), numerical results (such as LD_{50}, NOAEL, DT_{50} etc.), metabolites observed etc.*
Reasons for why the study is not considered relevant/reliable or not considered as key study:	*the reasons should be clearly specified*

3. Bordeline cases

In case of borderline cases (e.g., studies considered as supplementary/indicative), the AGG recommends that the GTF2 submits a complete study summary (section 1. above).

4. Obsolete exposure and risk assessments

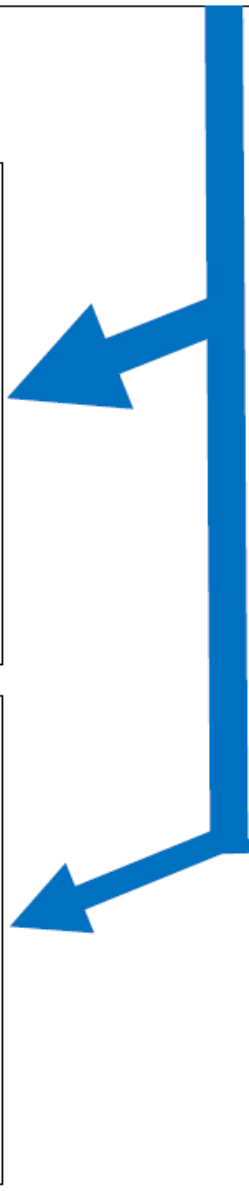
It is not necessary to repeat or summarise any of the exposure and risk assessments from the old dossiers that have become obsolete due to development of guidance. For instance, this may refer to human exposure assessment, PEC-calculations, kinetic assessments in e-fate.

ADVICE TO GTF2:

HOW TO PRESENT THE LITERATURE SEARCH

IN THE DOSSIER TO BE SUBMITTED JUNE 2020

The literature search should be carried out and presented as recommended in the EFSA Guidance EFSA Journal 2011;9(2):2092) including its recently published Appendix, available at the EFSA Journal.



Rapid assessment of titles/abstracts: Articles that are considered as **not relevant**:

Not necessary to submit articles or study summaries but justification needed at a general level, i.e. criteria used to classify references as being clearly non-relevant.

Detailed assessment of full text of articles: Articles that are considered as **not relevant** **or** considered **not reliable**:

Necessary to submit articles and statement with the reason of rejection (no study summaries).

Detailed assessment of full text of articles: Articles considered as **relevant and reliable**:

Necessary to submit articles. A detailed study summary should be provided in the relevant section of Doc MCA/MCP.

For presentation of detailed study summary, reference is made to EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances (27 March 2019, doi: 10.2903/sp.efsa.2016.EN-1612).