

Minutes of the pre-presubmission meeting AGG-GTF2 on the renewal of Glyphosate

Date: Thursday, July 4, 2019
Time: 09.00 – 11.20 h
Location: Via teleconference

1. Opening

The chair explains that a pre-presubmission step did not exist until today and is created especially for this project, because of the complexity of procedural and organizational matters.

The Glyphosate Task Force (GTF2) thanks AGG for this opportunity.

2. Aim of the meeting

Exchange of information between AGG and GTF2, preparing the agenda for the presubmission meeting.

Planning is to organize 3 presubmission meetings on the following topics:

- 1) General and procedural issues
- 2) Technical issues of tox/residues
- 3) Technical issues of fate/ecotox

All meetings will be face to face, location in Brussels and will take place after the summer.

Depending on the outcome there can be a follow up meeting with GTF2 and AGG. EFSA will be informed and will participate even if the amendments to the General Food Law are not yet implementable.

AGG will draft a timetable.

GTF2 agrees with this proposal.

3. AGG: information concerning organization and rules of procedure

- Introduction AGG:

Due to the complexity of the dossiers, AGG is formed to do the assessment of the renewal dossier of glyphosate; the group of four equal reporting member states is a novelty and the Regulation (EU) No 844/2012 is amended to make this possible.

All four members are acting on equal footing and are jointly responsible for the final assessment and sending the report to Commission, EFSA and ECHA.

- Steering Committee:

For organizational matters a steering committee with executive powers has been set up, which is responsible for the whole process. In the steering committee decisions are taken, reports are discussed and the final decision is taken before sending in the assessment report to Commission, EFSA and ECHA.

The steering committee is the sole representative of AGG.

- Contact point:

All communication between the GTF2 and AGG members will take place through a central email address and telephone number, organized by the EU Commission.

- General outline internal way of work:

Each AGG member is a principle authority for different parts of the dossier. The chapters of the Assessment Report will be written by one of the members and will be peer reviewed by the other members. The complete assessment however will be signed by all 4 members as they have the same responsibility for the final outcome.

- **Practical issues:**
EFSA will participate in the presubmission for glyphosate. Technical issues raised during the assessment can be discussed with EFSA if necessary. Its involvement is according to the new procedures slightly more than with earlier renewals. After the submission of the draft RAR, EFSA will take the lead and is responsible for the commenting round and the final opinion according to the normal process. The Commission will not take part; the assessment is only the responsibility of AGG and EFSA.
- **Dossier format:**
The latest Caddy XML format is to be used, so text and tables can be copied.
A dossier has to be submitted to each member of the AGG.
In relation to the discussion concerning plagiarism, it must be clear which parts are written by the GTF2 and which by AGG. Therefore AGG will adhere to the latest format (dated March 2019) as published by Commission on their website.
- **Guidance:**
The new EFSA Administrative guidance published March 2019 has to be used. According to the new criteria there is a need to perform an ED assessment and it must be clear whether there are new studies needed.
- **Fees:**
 - Each member will present an invoice for its own part of the assessment.
 - The overhead costs for the AGG, organization of meetings etc. will be partly billed on behalf of the AGG and partly included in the national fees.Details will be sent later.

4. Taskforce: general outline of presubmission- and submission approach / questions for AGG

GTF2 presents their presentation as included. The outcome of the discussion of the presentation is listed under point 5, Wrap up.

Introduction membership

GTF2 explains that companies which are members of the taskforce must be an entity or have contracts to produce glyphosate, as required by Regulation (EC) No. 1107/2009. Board members (5 in total) are approved suppliers in the EU, own a significant data package and have the desire and technical expertise to participate fully in the activities of GTF2.. Currently there are 7 associate members of the taskforce which do not have a significant data package or do not wish to participate in the Board. The decisions are taken by the board members of whom Bayer is the lead member and consequently handles the contact with authorities.

GTF2 is supported by an independent legal counsel, secretary and treasurer. They are independent of the companies of the GTF2.

Compared to 2012 the number of members is decreased, partly due to many consolidations by mergers and acquisitions (colors show the connections of the companies). A company without a color is not a member of the taskforce, but GTF2 is trying to gain access to their studies because GTF2 to assure a complete dossier.

The Regulatory working group (RWG) has interactions with the RMS and is responsible for the notification and submission of the dossier. It is supported by a technical working group (for each aspect of dossier). Knoell Germany GmbH is the consultant with the important task of assisting with the compilation of the dossier and submission. As Knoell is responsible for completing the final dossier on behalf of the GTF2 and for dealing with company confidential information, they play a critical role within the task force.

The Public Affairs Group is responsible for the provision of information concerning glyphosate to stakeholders through a web site, newsletters, etc.

For confidential data Knoell as consultant should be contacted.

5. Wrap up

	Topic	Action / action by	Deadline
1	Access to studies owned by entities who are not a member of the GTF2.	Topic PSM	
2	Single contact point for GTF2 for all issues will be the Regulatory Working Group (RWG). For issues concerning confidentiality, GTF2 will present a solution. Preferably Knoell will be the contact point for the entire dossier. Setting one single contact point, including for confidential information, would be a preferable option.	GTF2 to analyse how to improve the foreseen contact point system and to inform AGG	Before PSM
3	Reference specification is unknown to GTF2 members. How to deal with that? How does the EU specification relate to the FAO specification?	AGG to check with EFSA	Before PSM
4	Format of application and dossier in general, involving new EFSA administrative guidance.	Topic PSM	
5	Evaluation of all studies or only studies that are not part of the original dossier of 2012 and referring to all studies as from 1998.	Topic PSM	
6	Confirmation that only guidance is to be used which are into force at the time of submission and that there will be no changes of guidances or requirements during the procedure?		Before PSM
7	Possibilities to contact AGG before the submission of the dossier: there could be the need to contact or organize pre-check meetings or pre-admissibility checks. These could be included in the timelines. AGG will get back on this subject.	AGG to inform GTF2	Before PSM
8	CLH part: AGG will check what must be done and what will be peer reviewed by ECHA.	Topic PSM	
9	Transparency: communication between GTF2, AGG, EFSA and Commission. GTF2 aims at maximum transparency and want to publish, amongst other, also communication with AGG and EFSA. AGG will come back on this topic. It is important to take note that the competent authorities have their own rules on transparency and also have obligations towards ministers and, through them, the national parliaments. If the GTF2 intend to publish emails and so on that refer to participants of meetings, it has to be checked with the parties involved in meetings and publications.	To be checked by AGG	Before PSM?
10	Public database of studies in advance of the General Food law requirements: AGG will contact EFSA and come back on this.	AGG to check with EFSA	Before PSM or during PSM

11	Public comments: possibility for public comments. AGG will contact EFSA.	AGG to check with EFSA	Before PSM or during PSM
12	Procedure of the disclosure of scientific studies under the General Food Law: AGG will contact EFSA.	AGG to check with EFSA	Before PSM or during PSM
13	Literature review before 2012: AGG will contact EFSA about guidance for literature review.	AGG to check with EFSA	Before PSM or during PSM
14	Receipt by AGG of all 7,000 studies identified in the literature review or only the relevant ones for the dossier. AGG will receive a document providing criteria for the search and for the inclusion of the publication as being relevant. AGG will come back on this topic before or during the presubmission meeting.	Check by AGG	Before PSM or during PSM

Remarks presubmission meetings:

- AGG expect that 3 presubmission meetings are necessary and these questions will be helpful to prepare 3 agenda's. Industry will prepare a proposal for the agenda so that issues can be added.
- AGG consider it important to have two face-to-face PSMs. Location will be Brussels/Belgium.
- The number of delegates is up to the applicants to decide, but is it helpful to have a spokesperson and to pay consideration to the size of available rooms in European buildings.
- Level of consultation: it is important to have AGG as organizer, but EFSA is in the lead with certain issues, so consequently there will be a division of responsibilities.
- Detailed discussions on the review can be held during PSMs.

The chair thanks the attendees for this productive meeting.