Glyphosate Renewal Group

28 September 2022

Klaus Berend
European Commission
DG SANTE - Unit E.4 - Pesticides and Biocides
1049 Brussels
[redacted]

The Glyphosate Renewal Group input for the 13-14 October SCoPAFF meeting

Dear Mr Berend,

As you know, the Glyphosate Renewal Group (GRG) is a group of companies seeking the renewal of the EU authorisation of the active substance Glyphosate which is going to expire in December 2022. To this end, the GRG's member companies joined resources and efforts to prepare a single dossier with scientific studies and information on the safety of Glyphosate.

In view of the SCoPAFF phytopharmaceuticals-legislation meeting on 13-14 October 2022, the GRG would like to inform you and ask you to share the GRG's ask for Member States representatives to support the extension of the current Glyphosate authorisation '(…) for a period sufficient to examine the application', as provided for in Art. 17 of Regulation (EC) No 1107/2009[1].

This request is based on the strong science-based rationale for an extension of the Glyphosate authorisation (see no 1 and 2 below) and EFSA´s and ECHA´s communication on the updated timeline of the re-evaluation process (see no 3 below).

In addition, the GRG wants to emphasize that it has thoroughly addressed the unprecedented number of stakeholder comments received during the public consultation, including carrying out a comprehensive public literature review in line with the applicable EFSA guidance, a detailed description of which has been incorporated in the scientific dossier and made available on the GRG website in order to address possible concerns by the public about the adequacy of the literature review (see no 4 below).

More specifically:

1) Preliminary results of the scientific evaluation show that Glyphosate meets approval criteria for human health and environmental safety.

The GRG would like to highlight that following the evaluation of the scientific dossier, the **Assessment Group on Glyphosate (AGG)'s draft Renewal Assessment Report** (dRAR), published on June 15, 2021, concluded that:

[1]Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Article 17- Extension of approval period for the duration of the procedure

Where for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal, a decision shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), postponing the expiry of the approval period for that applicant for a period sufficient to examine the application.

A Regulation postponing the expiry for a period sufficient to examine the application shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(5) where an applicant could not give the three years' notice required under Article 15(1) because the active substance was included in Annex I to Directive 91/414/EEC for a duration which expired before 14 June 2014.

The length of that period shall be established on the basis of the following:

(a) the time needed to provide the information requested;

(b) the time needed to complete the procedure;

(c) where appropriate, the need to ensure the establishment of a coherent work programme, as provided for in Article 18.

- **Glyphosate meets the approval criteria for human health**;
- Taking all the evidence into account (i.e., animal experiments, epidemiological studies, and statistical analyses), **the classification of Glyphosate is not justified:**
  - **with regard to carcinogenicity;**
  - as toxic for reproduction;
  - as for germ cell mutagenicity, genotoxic or mutagenic;
  - for specific target organ toxicity, neither for single nor repeated exposure respectively;
- no chronic or acute consumer risk is expected from the treatment of crops with Glyphosate, according to the representative uses for the current renewal process.

2) ECHA does not propose change to hazard classification

On May 30, 2022, ECHA announced the conclusion of its review of the classification of Glyphosate. Based on a wide-ranging review of scientific evidence, the ECHA Risk Assessment Committee (RAC) concludes that classifying Glyphosate as a carcinogen is unjustified. Further, the RAC found that the available scientific evidence does not meet the criteria to classify Glyphosate for specific target organ toxicity, or as a mutagenic or reprotoxic substance.
These findings confirm that no new classification is proposed for Glyphosate, the existing ones for eye irritation and chronic aquatic toxicity are proposed to be maintained.

The GRG would like to underline that ECHA's conclusions are consistent with the dRAR.

Furthermore, the AGG and ECHA's findings demonstrate that Glyphosate meets approval criteria for human health and that classifying it as carcinogenic is unjustified. As such, it does not pose immediate concerns for human health, animal health, or the environment.

3) The reasons for the revised timeline

The GRG would like to raise the awareness of the SCoPAFF members that the consultations carried out by EFSA and ECHA on the draft assessments of Glyphosate attracted an unprecedented number of comments, confirming the high level of interest in Glyphosate. This demonstrates the high level of public participation, underlining the importance of transparency in the evaluation of active substances in the EU.

The input received from the consultations, together with the replies received by EFSA from the applicant (GRG) in response to its request for additional information, added a significant amount of information. This comes in addition to the fact that the dossier already contained far more scientific data than is usually available for such assessments. [2]

Against this background, EFSA and ECHA have revised the timeline for the remaining steps in the re-evaluation process and issued a communication in which they have explained the reasons for the update of the timeline.

4) Public literature review in line with the detailed EFSA guidance

Plant Protection Product (PPP) producers that apply for approval and reapproval of their active substances in the EU are required to ensure that all relevant scientific information, including publicly available scientific articles, is reviewed. To facilitate the review process, EFSA has developed detailed guidance on how to carry out a comprehensive public literature review, which the GRG has followed closely.

[2] Glyphosate: EFSA and ECHA update timelines for assessments, 10 May 2022 [link]

In the Glyphosate reapproval process, the GRG reviewed thousands of public literature articles and added its assessment of several hundred additional public literature articles in response to requests from the responsible Member States, EFSA, and the public.

A detailed description of the literature search and review, including article titles and detailed justifications for the GRG's assessment of relevance and reliability of these literature articles, can be found in the dossier submitted to the AGG and is also made available on the GRG website as part of the GRG's commitment to transparency.

Should you have any questions regarding The Glyphosate Renewal Group input, please do not hesitate to contact us.

The Glyphosate Renewal Group

This letter will be published on the GRG website and will be available at the following link.

Annex 1 – EFSA Guidance, and the Appendix on performing and presenting the literature search [link, link]
Annex 2 - Response to various requests for clarifying the approach used for the literature review in view of the comments/concerns raised by several commenting parties during the public consultation [available to download via this link]
Annex 3 - Procedure and outcome of the draft Renewal Assessment Report on glyphosate, 15 June 2021 [link]
Annex 4– Glyphosate: no change proposed to hazard classification [link]
Annex 5- Glyphosate: EFSA and ECHA update timelines for assessments [link]