



European Food Safety Authority (EFSA)
Scientific Evaluation of Regulated Products Department
Head of the Pesticide Peer Review Unit

CC:

- ANSES France,
 Chair of the Assessment Group on Glyphosate (AGG),
- EU Commission, DG SANTE,
 Head of Unit Pesticides and biocides,

By e-mail

Follow-up on Glyphosate Renewal Group (GRG) proposal and EFSA response on making the 2020 glyphosate renewal dossier and new study reports publicly available, including an opportunity for public commenting (Ref. MT/ss – OC-2020-23317245)

Dear ,

Thank you for your letter from 15-May-2020 in response to earlier correspondence from GRG to EFSA (15-April-2020 and 4-May-2020) about the proposed activities of GRG in terms of transparency regarding the glyphosate renewal dossier.

GRG appreciates EFSA's analysis of and positive response to our transparency proposal and the offer to link from EFSA's website to the GRG website resources that will make the summary dossier and study reports publicly available.

Consequently, GRG will continue our preparation towards the exemplary and unprecedented implementation of transparency measures for glyphosate, to provide a route to access the full non-confidential part of the 2020 dossier and the reports of studies commissioned by the GRG or its members, once admissibility has been confirmed in July this year.

May 22, 2020

Bayer AG Crop Science Division Global Regulatory Affairs

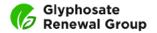
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Access to the scientific dossier and study reports of the 2012 glyphosate application is already given for any interested person, via our recently launched GRG website www.glyphosate.eu.

GRG is applying the principles of the General Data Protection Regulation (GDPR) (EU) 2016/679 as EFSA has to apply the corresponding EU Directive 2018/1725 for the sanitization of all dossier documents and study reports that can be accessed via our GRG website, as well as for the sanitization of the 2020 renewal dossier documents that will be provided to regulatory authorities during the renewal process, to protect personal data and confidential business information in line with applicable data privacy provisions.

Regarding the GRG proposal of a public consultation on the 2020 summary dossier and new study reports (special procedure), to be held after completion of the admissibility check, GRG is of the opinion that EFSA as an independent body would give the highest credibility to such a process, to address any concerns by the public about the appropriate uptake of any incoming comments. Therefore, the GRG cannot offer a public commenting phase with the independence that the General Food Law foresees with the competent authority as evaluation body.

However, the GRG is offering the opportunity to the public to submit any comments via our GRG website contact form (accessible already now on www.glyphosate.eu/get-in-touch/), and GRG will thoroughly evaluate any incoming comments, especially in case information about additional scientific data is provided that should be considered in the frame of the glyphosate renewal evaluation. GRG will apply the same principles of assessing relevance and reliability for such incoming public comments like we are doing for any peer reviewed public literature in the frame of the literature review report according to the provisions of the EFSA Guidance "Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) 1107/2009" and according to the updated Appendix to this Guidance document, and those comments evaluated as relevant through the guidance will be included during the evaluation process at the foreseen timepoints.





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GRG notes that there are currently at least four websites related to the glyphosate EU renewal process:

- The European Commission DG SANTE AGG page¹
- The EFSA page²
- The ANSES France page³
- The GRG website⁴

In line with the EFSA proposal, the GRG welcomes for the owner of these websites (i.e. DG SANTE, EFSA, ANSES and GRG) to provide links to each other's sites on respective websites, to facilitate an easy overview to the public about available resources and to promote access to the transparent documentation of the renewal process.

The GRG will continue keeping EFSA, AGG and DG SANTE informed about the progress of our glyphosate transparency initiative, and GRG is welcoming continued exchange with the competent authorities about the topic of increasing public trust in the European regulatory process via applying the principles of maximum transparency.

Please contact me in case you have any questions or comments.

Yours sincerely,

Glyphosate EU Regulatory Lead, Bayer AG Chair of GRG Regulatory Working Group

¹ https://ec.europa.eu/food/plant/pesticides/glyphosate/assessment-group_en

² https://www.efsa.europa.eu/en/topics/topic/glyphosate

³ https://www.anses.fr/en/content/glyphosate-0

⁴ https://glyphosate.eu