

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

[REDACTED]

CC:

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

By e-mail

**Glyphosate Renewal Group (GRG) proposal for making the 2020
glyphosate renewal dossier and new study reports publicly
available, including an opportunity for public commenting**

Dear [REDACTED],

The objective of GRG and its member companies is to be as transparent as possible with the preparation and submission of the glyphosate renewal dossier by 15-June-2020. Specifically, the GRG intends to proactively implement the provisions of the Amended General Food Law (GFL) Regulation (EU) 2019/1381, before the Date of Application which is 27-March-2021, to the extent possible with the glyphosate renewal dossier. The Assessment Group on Glyphosate (AGG) was informed of our intentions in the first AGG/GRG pre-submission conference call on 4-July-2019, and intentions were further discussed with the AGG and EFSA at the second pre-submission meeting on 27-September-2019.

GRG would like to explain in more detail our considerations regarding this topic in this letter.

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April 15, 2020

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GRG proposal

The GRG proposes:

- 1) Disclosure of the dossier: The glyphosate renewal dossier to be made publicly available after the admissibility check in July this year, to give the public the opportunity to see the content of the dossier, including the new study reports (approx. 50 reports).
- 2) Public commenting: A special public consultation procedure on the 2020 summary dossier and the new study reports (approx. 50 reports) to be organized and coordinated mainly by EFSA, to determine if other relevant scientific data or studies are available (based on Article 32c.2 of the GFL Regulation (EU) 2019/1381) that have not been considered so far in the glyphosate renewal dossier.

It is our understanding that the next step now is to discuss with EFSA, AGG and DG SANTE a specific procedure for the two proposals mentioned above. GRG would like to provide the following proposals, as a basis for such discussion.

Disclosure of the dossier

GRG's preference is that the dossier and the new study reports are disclosed by EFSA on their website, to guarantee independent interaction between the public and the regulatory authorities. If this is not feasible, the GRG would offer to evaluate the opportunities to disclose these documents through its GRG homepage (glyphosate.eu).

Key dates and Actions

- 1) Submission of the complete renewal dossier, summaries and studies by GRG to AGG and EFSA by 15-June-2020, which includes:
 - a) The complete dossier, including confidential parts for regulatory authorities
 - b) The justification for confidential business information based on Article 63 of Regulation (EC) No 1107/2009, and personal data based on Regulation (EU) 2016/679

2) Admissibility of the complete dossier is confirmed by EFSA and AGG, and the claims for confidentiality by 15-July-2020.

3) Disclosure of the complete dossier and new study reports

- a) From 15-July-2020, disclosure of the GRG-sanitized summary dossier by EFSA on their website in the Register of questions section (standard procedure based on Article 10 of Regulation (EC) No 1107/2009). GRG would kindly request DG SANTE and EFSA to consider applying sanitization of all personal data, based on the General Data Protection Regulation (EU) 2016/679, in line with data privacy provisions, once the completeness check has been approved by EFSA/AGG.
- b) Shortly afterwards, disclosure of the GRG-sanitized new study reports that are part of the renewal dossier (approx. 50 reports). This will be a special procedure for disclosure, as the basis for the special public consultation by EFSA (see below). The GRG will provide a sanitized version for confidential business information based on Article 63 of Regulation (EC) No 1107/2009. GRG would propose again (see above) sanitization of all personal data, based on the General Data Protection Regulation (EU) 2016/679.
- c) Studies part of the previous dossier: Due to the large volume of study reports that were part of the previous glyphosate (renewal of) approval submissions in EU, the GRG cannot guarantee at this point the sanitization of all previous documents in time by the dossier submission date in June. GRG will make these documents available for ordering by the public, and apply a sanitization-on-demand procedure via a single document online ordering process through the GRG homepage (glyphosate.eu), starting mid-April 2020. The final sanitized documents can also be provided to EFSA, if EFSA decides to establish a similar ordering concept through its homepage. If this is not feasible, we believe that a reference to our ordering platform on 'glyphosate.eu' can be made to enable access for interested person. GRG proposes again (see above) sanitization of all personal data, based on the General Data Protection Regulation (EU) 2016/679.

**Public consultation of the summary dossier and new study reports
(Special procedure)**

GRG proposes that the public consultation should be based on 1) the new summary dossier, and 2) the new study reports. As explained above, the large volume of glyphosate studies submitted in the previous EU (renewal of) approval submissions (more than 800 studies) makes it practically very challenging to make them all publicly available in sanitized form on a website for download.

Only approx. 100 study reports have been already sanitized for CBI and personal data. For the remaining, so far un-sanitized older studies GRG proposes to apply a sanitization-on-demand procedure, once a concrete request for a specific study is obtained (see point 3c) above). Sanitization will be done by GRG for CBI and personal data, based on the General Data Protection Regulation (EU) 2016/679.

GRG proposes that the public consultation will be organized by EFSA, from a link on their website for a defined period, e.g. 30 days. GRG sees great value in having this public consultation hosted by EFSA as an independent body. This consultation will determine if other relevant scientific data or studies are available (based on Article 32c.2 of Regulation (EU) 2019/1381). GRG proposes that a summary of the public comments received should be collated by EFSA/AGG and disclosed on the EFSA website.

GRG offers to take up any feedback provided by EFSA and AGG on actions arising from the public comments, especially with respect to additional information that could be provided by GRG at the latest during the stop the clock period (article 13.3 of Regulation (EU) No 844/2012).

Specific questions to EFSA

- 1) When EFSA issues to data owners a request based on Freedom of Information it refers to the 'public access to documents' Regulation (EC) No 1049/2001. GRG legal opinion is that Regulation (EU) 2016/679 now applies. GRG would like to ask why there is no reference since 2018 to the more recent EU GDPR regulation on protection of personal data (Regulation (EU) 2016/679)?
- 2) Since GRG legal opinion is that Regulation (EU) 2016/679 now applies, GRG proposes to apply this also to the sanitized

summary dossier for disclosure by EFSA, i.e. sanitization of all names. Is EFSA in agreement with this approach?

- 3) For the special procedure, the GRG proposes to redact all names in the new study reports, consistent with Regulation (EU) 2016/679. Is EFSA in agreement with this approach?
- 4) How will EFSA manage the comments received from the public consultation? Will comments be bulk answered similar to a recent consultation made by EPA¹?
- 5) Can EFSA confirm that the sanitized summary dossier and the sanitized new study reports should be sent to EFSA only once the completeness check has been confirmed?

Thank you for considering the GRG's proposals and questions, and we are looking forward to your comments.

Yours sincerely,



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

¹ GRG would like to provide the following links as an illustration of a recent glyphosate public commenting exercise: *General glyphosate reg review docket*: US EPA Gly Registration Review Public Docket (<https://www.regulations.gov/docket?D=EPA-HQ-OPP-2009-0361>); *A few examples of responses to public comments*: Response from the Pesticide Reevaluation Division to Comments on the Glyphosate Proposed Interim Decision (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-14443>); Glyphosate Response to Comments on the Proposed Interim Decision Regarding the Human Health Risk Assessment (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-14444>); *response to publications posted during comment period*: Glyphosate: Epidemiological Review of Zhang et al. (2019) and Leon et al. (2019) publications for Response to Comments on the Proposed Interim Decision (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-14445>); Response to Public Comments on the Preliminary Ecological Risk Assessment for Glyphosate (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2341>); Glyphosate: Response to Comments on the Human Health Draft Risk Assessment (<https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2343>)