

**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

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May 4, 2020

[REDACTED]

Bayer AG
Crop Science Division
Global Regulatory Affairs

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Germany

**Follow-up on 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],

Following up on our letter from 15-April-2020, we would like to inform you
of the launch of our new GRG website www.glyphosate.eu.

The website is a demonstration of the GRG's "Commitment to
Transparency". The GRG is providing access to all the information part of
this renewal process. In particular, the GRG is voluntarily implementing
the transparency 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 we can make it possible for the European
glyphosate renewal process.

To fulfil our commitment to transparency, the website is the platform to
host information on glyphosate and, most importantly, provide access to
key documents related to the regulatory process for seeking renewal of
approval of glyphosate in the EU.

[REDACTED]
www.bayer.com

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Those documents include:

- **Minutes of the pre-submission meetings** held between the GRG and AGG, with EFSA as an observer. Any minutes of future meetings and correspondence in letter format to be made available as well.
- The **official application** submitted by the GRG to AGG in December 2019 that includes the list of new studies commissioned by GRG.
- The **scientific dossier of the 2012 application**.
- We also plan to provide a route to access the **full non-confidential part of the 2020 dossier**, once admissibility has been confirmed in July this year.

The scientific dossier of the 2012 application is composed of:

- the list of public scientific literature on glyphosate,
- the dossier summary documents (also available on EFSA's website) and
- the reports of the studies commissioned by the GRG or its members.

GRG would like to briefly explain the already implemented access to study reports that were part of the 2012 dossier:

- Interested parties can submit a request via the website contact form (one request per study).
- Once a request has been submitted, the GRG will provide the study to the requester in a sanitized form to protect personal data and confidential business information, based on the General Data Protection Regulation (GDPR) (EU) 2016/679, in line with data privacy provisions.

As explained above, the GRG is planning to use the functionality of this website to also provide access to the 2020 summary dossier and new study reports in due course, so we would like to illustrate the procedure to allow EFSA to get a lively impression of our set-up (see **Appendix**).

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As communicated in our letter from 15-April-2020, GRG would very much appreciate EFSA's input and comments regarding the described proposal and procedure, and we would like to ask for a conference call in order to discuss details and the questions raised in our letter.

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

Yours sincerely,

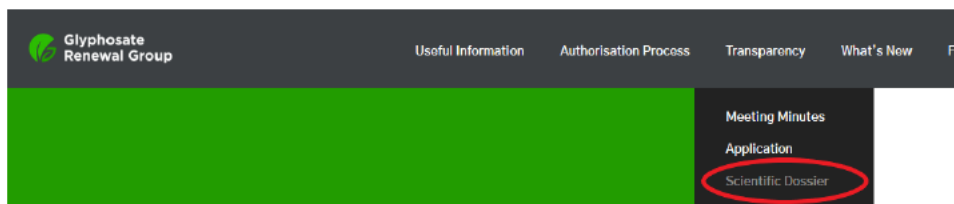


Glyphosate EU Regulatory Lead, Bayer AG
Chair of GRG Regulatory Working Group

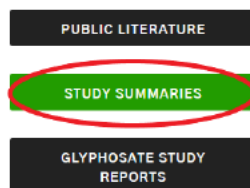
Appendix:

Step-wise description of summary dossier documents and study report access on the GRG website www.glyphosate.eu:

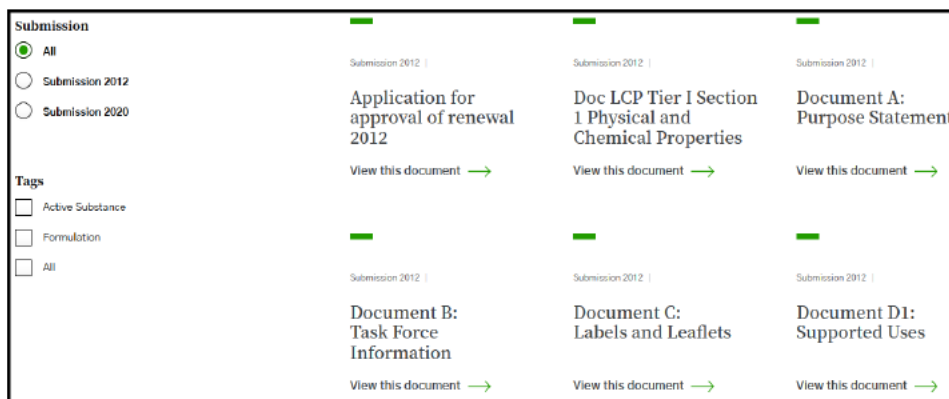
- 1) In the top main menu of the homepage, go to “Transparency” and to “Scientific Dossier”:



- 2) In the side menu of the “scientific dossier” page, go to “Study Summaries” to get access to the summary dossier documents of the 2012 renewal dossier:

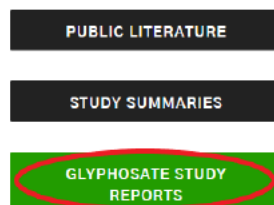


- 3) On the “study summaries” page the summary dossier documents of the 2012 renewal dossier (also available on EFSA’s website) are available for download. The summary documents are sanitized according to GDPR, i.e. all personal data is redacted.



GRG is planning to make the summary documents from the 2020 glyphosate renewal submission available in the same format on this website, again sanitized according to GDPR, i.e. all names redacted. For the time being, clicking the button “Submission 2020” leads to a “coming soon” message.

- 4) In the side menu of the “scientific dossier” page, go to “Glyphosate Study Reports” to get access to the single document ordering functionality:



- 5) On the “glyphosate study reports” page you can open the “Reference List for Glyphosate study ordering”, and this will provide a reference list where full study reports from the 2012 submission can be requested by clicking the hyperlink “request study report” in the rightmost column “Hyperlink to order the document”:

Section 1 - Physical and chemical properties

Annex point	Details to Annex point	Year	Author(s)	Title Report No. Source GLP status published at not	Data protection claimed	Owner	Hyperlink to order the document
IIA 1.10 / 01; IIA 4.1.4 / 01	Physical and chemical properties/ Identity, content and structure of isomers, impurities and additives (Section 01, Point 2)	2013	[REDACTED]	Analytical Reference Standard, Certificate of Analysis, Expiration Extension 3034 Monsanto GLP: no not published	Y	Monsanto	request study report
IIA 2.1.1/01; also filled under: IIA 2.1.3/01	Physical and chemical properties/ Melting point, freezing point or solidification point, purified a.s. (Section 01, Point 2)	1989	[REDACTED]	Determination of the melting point of the test sample Glyphosate acid 99,9% acc. to Report No.: NA 89 9641/1 Nitex Institut GLP: yes not published	N	Monsanto	request study report

- 6) After clicking the hyperlink to order a specific study, the “Report Order Form” will open in a separate browser window and the entry of certain personal information is required to proceed.
- 7) Once the interested user has verified his e-mail address and accepted the terms and conditions, a process will start to redact the requested study (sanitized according to GDPR, i.e. all names redacted) and to send the requested sanitized pdf of the full study report to the requester (via e-mail).

You will note that currently certain glyphosate studies are not accessible since there is no “request study report” hyperlink in the reference list. The reason is that these study reports are owned by companies that are not a member of the GRG. GRG is working with these companies to obtain their consent to provide these currently not accessible reports as soon as possible to the interested user on request.

GRG is planning to make the new study reports of the 2020 glyphosate renewal submission (approx. 50 reports) available in the same way on our website, again sanitized according to GDPR, i.e. all names redacted. For the time being, clicking the button “Submission 2020” on the “Glyphosate Study Reports” page leads to a “*coming soon*” message.