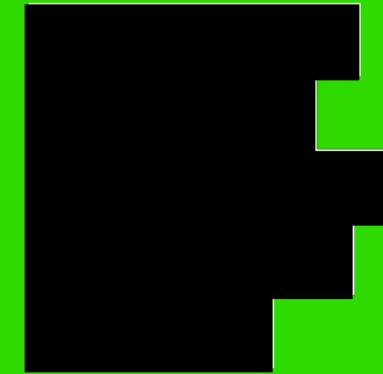


GRG EFSA CALL

MAKING THE 2020
GLYPHOSATE
RENEWAL DOSSIER
PUBLICLY AVAILABLE



Monheim, 12 June 2020

Participants

- [REDACTED] (Bayer, head of Regulatory Affairs Crop Protection)
- [REDACTED] (Bayer, Law, Patents & Compliance)
- [REDACTED] (Bayer, Senior Regulatory Scientific Affairs Manager)
- [REDACTED] (Bayer, Glyphosate EU Regulatory Lead)
- [REDACTED] (Syngenta, Regulatory Affairs)

Topics

- Glyphosate Renewal Group (GRG) **transparency commitments** and website
- **GRG / EFSA communication**
- Considerations on a **public commenting phase** after dossier submission
- Applicable **sanitization principles** for dossier and transparency
- Making correspondence and presentation publicly available

The GRG Transparency Commitments

Everyone can access information on our Glyphosate Renewal Group website www.glyphosate.eu to participate in the renewal in the most informed manner

- ✓ Topics discussed with AGG in preparation of the submission (**pre-submission meetings**)
- ✓ New studies that are being prepared (**Application document**)
 - These studies will be part of our dossier,
 - irrespective of the findings
- ✓ Easy access to **study reports from the 2012 submission** established
- Easy access to **new study reports of the 2020 submission** after admissibility confirmation
- **Public commenting** on dossier after submission (according to GFL) not planned by EFSA



Summary of communication to EFSA: Making 2020 renewal dossier publicly available

Letters to EFSA, AGG, DG SANTE on April 15 and May 4

- Questions posed to EFSA:
 - Will **EFSA be in the lead** for making the dossier publicly available in July?
 - How to handle **access to new study reports**?
 - Will EFSA/AGG organize a **public commenting** in August and how to **handle incoming comments**?
 - What **redaction rules** will EFSA accept? GRG proposal: Redact all names according to GDPR.
- Follow-up letter May 4:
 - **Explain the transparency section** of our new GRG website
 - Step-wise **visualization** of dossier summary download and **study report ordering functionality**

Summary of communication to EFSA: Making 2020 renewal dossier publicly available

Letter from EFSA, copy AGG and DG SANTE from May 15

- *"We encourage the GRG to publish the studies and launch a public consultation on their own website, and we make ourselves available to link this activity in the EFSA website."*

GRG reply letter sent May 22:

- GRG will continue our preparation towards providing a route to access
 - the full **non-confidential part of the 2020 dossier**
 - the **reports of studies commissioned** by the GRG or its members (as stated in the Application document)

Glyphosate Scientific Dossier Submitted

On Monday, 8 June, the Glyphosate Renewal Group submitted the scientific dossier in view of a new evaluation and risk assessment of the active substance glyphosate. The submitted scientific dossier, including 100 newly performed studies, will be accessible via this website.

[FIND OUT MORE](#)

Our Commitment to Transparency

To respond to the demand for greater transparency, the Glyphosate Renewal Group will proactively meet the new provisions of the EU General Food Law before the legislation comes into force. In doing so, the Glyphosate Renewal Group will make available all the files in the scientific dossier.

[MORE ABOUT TRANSPARENCY](#)

Study Report Ordering Process

Glyphosate Renewal Group

Useful Information Authorisation Process Transparency What's New FA

Meeting Minutes
Application
Scientific Dossier

PUBLIC LITERATURE

STUDY SUMMARIES

GLYPHOSATE STUDY REPORTS

Submission

All

Submission 2012

Submission 2020

Reference List for Glyphosate study ordering

Download ↓

Annex point	Details to Annex point	Year	Author(s)	Title Report No. Source GLP status published or not	Data protection claimed	Owner	Hyperlink to order the document
IIA 5.2.1/14	Toxicological and toxicokinetic data/ Acute toxicity - Acute oral toxicity (Section 03; Point 5)	2007	[REDACTED]	Glyphosate Technical material: Acute oral toxicity study in rats (Up and Down procedure) Study No.: B02755; Syngenta Task No.: T007035-05 GLP: yes not published	Y	Syngenta	request study report
IIA 5.2.1/15	Toxicological and toxicokinetic data/ Acute toxicity - Acute oral toxicity (Section 03; Point 5)	2011	[REDACTED]	Glyphosate technical – Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Report No.: 10/218-001P GLP: yes not published	Y	Syngenta	request study report
IIA 5.2.1/16	Toxicological and toxicokinetic data/ Acute toxicity - Acute oral toxicity (Section 03; Point 5)	1995	[REDACTED]	Acute Toxicity Study of MON 0139 By Oral Administration in Mice Report No.: B-3101; Monsanto Study No.: XX-95-205 GLP: yes not published	Y	Monsanto	request study report
IIA 5.2.1/17	Toxicological and toxicokinetic data/ Acute toxicity - Acute oral toxicity (Section 03; Point 5)	1999	[REDACTED]	NUP5a99 62% glyphosate MUP: Acute oral toxicity study in rats Study No.: 7907 GLP: yes not published	Y	Nufarm	request study report

Page 39 of 186

- Report Order Form
- Accepting Terms & Conditions
- Receipt of sanitized study report

New study reports will be made accessible via the same route, including an option for „batch order“

Summary of communication to EFSA: Making 2020 renewal dossier publicly available

GRG reply letter sent May 22:

- **GRG cannot offer a public commenting phase with the independence that the General Food Law foresees** with the competent authority as evaluation body
- GRG is offering the opportunity to the public to **submit any comments via our GRG website contact form**
- **GRG will thoroughly evaluate any incoming comments**, applying the principles of assessing relevance and reliability
- **Comments evaluated as relevant through the guidance will be included** during the evaluation process at the foreseen timepoints

Summary of communication to EFSA: Making 2020 renewal dossier publicly available

GRG reply letter sent May 22:

- **GRG is applying the principles of the General Data Protection Regulation (GDPR) (EU) 2016/679**
 - for the sanitization of all dossier documents / study reports **accessible via our GRG website**
 - for the sanitization of the 2020 renewal dossier documents to be **provided to regulatory authorities** during the renewal process

THANK YOU!



**Glyphosate
Renewal Group**