# GLYPHOSATE PUBLIC COMMENTING PERIOD – *How to participate*

A presentation by the

**Glyphosate Renewal Group**

SEPTEMBER 2021

# *Purpose of this deck*

- This deck explains the practical steps to follow when participating in the EFSA and ECHA public commenting period on the active substance glyphosate, to gather comments on the Rapporteur Member State's Assessment Report (dRAR), which opened on 23 September 2021 and will remain open for a period of 60 days, until 22 November 2021.
- This deck can be used to illustrate to observers how to engage in the public commenting period and what to consider when preparing a submission.

## Key points explained in this deck

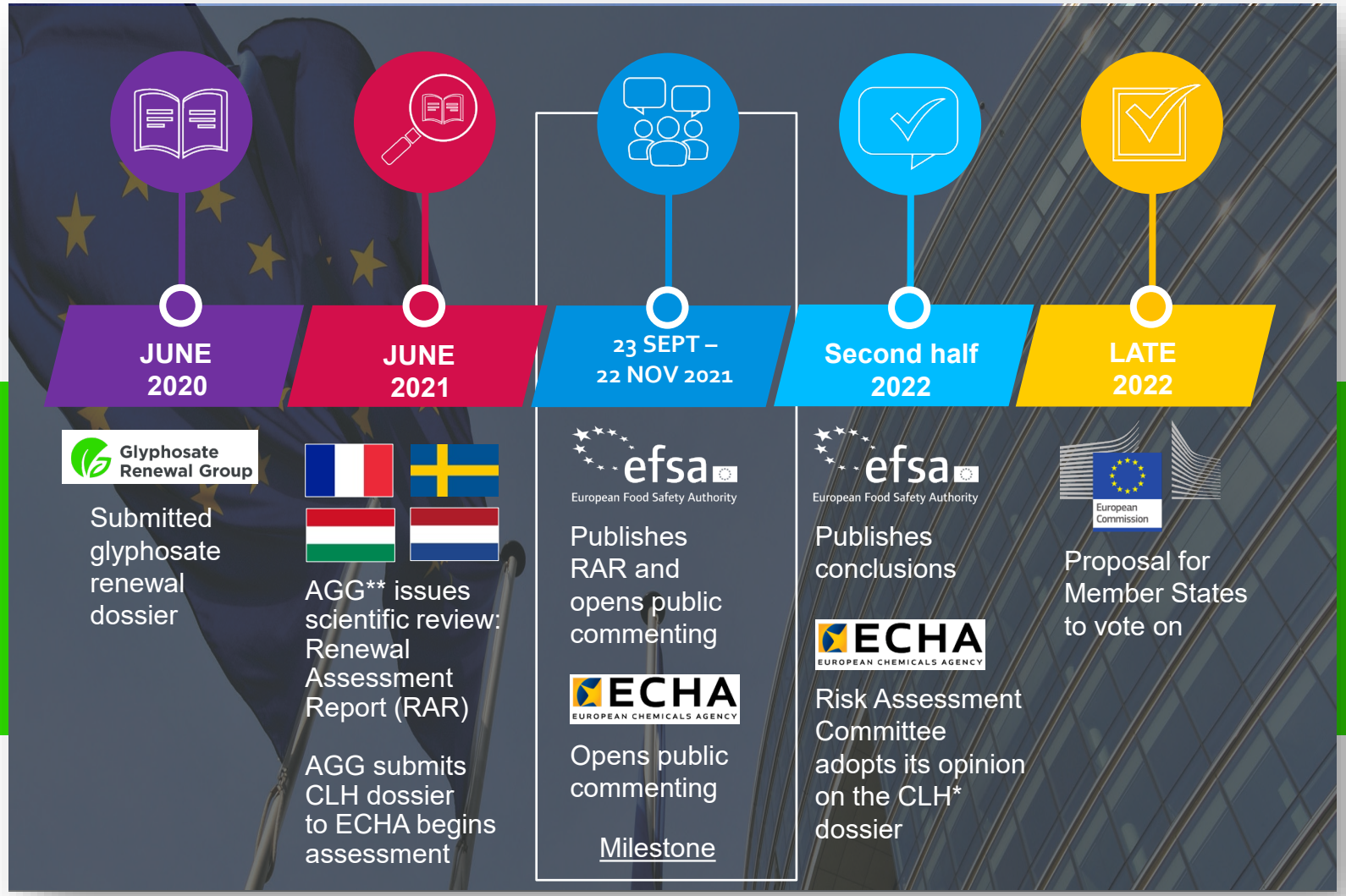
- The process targets engagement from scientist or regulators on specific data points.
- The practical steps necessary to participate in the public commenting period need to be considered by interested citizens when submitting comments.
- Unscientific, general and orchestrated comments are not taken into account by EFSA and ECHA.

# The EU Re-approval Process of Glyphosate

*/// EU Public Commenting Period /// September 2021*

Glyphosate Renewal Group

# *Written submissions of comments only via dedicated processes*




- The Glyphosate Renewal Group (GRG) as the applicant will submit written comments.
- EU member state regulators will submit their views.
- Written comments submitted during the public commenting period to ECHA and EFSA will be published in due course after the public consultation closes.

*CLH: Harmonised classification and labeling (Source: ECHA)

**AGG: Assessment Group on Glyphosate (Source: AGG)

# EFSA

# Renewal of an active substance

# Regulation (EC) No 1107/2009

*/// EU Public Commenting Period /// September 2021*

Glyphosate Renewal Group

efsa

European Food Safety Authority

# *EFSA: AGG assessment report and CLH report are made available **at the start** of the public commenting period on 23 September*

Open Public Consultations

15 items • Sorted by End Date • Filtered by All public consultations - Status, End Date

Search this list...

| | Public ... | Title | Food Domain | End Date |
|---|---|---|---|---|
| 1 | PC-0088 | Assessment Report on the active substance Glyphosate | Pesticides Peer Review (AIR) | 22/11/2021 |

Submissions can be made here - EFSA and ECHA

## Harmonised classification and labelling consultations

**Parties concerned are invited to comment on hazard classes open for consultation, which are indicated in the substance table below.**

The indicated hazard classes were assessed and concluded by the dossier submitter in their proposal for harmonised classification and labelling (CLH) of the substance.

A hazard class may be open for commenting even if the dossier submitter did not conclude that it warrants a classification. The CLH consultation lasts for **60 days** (unless specified otherwise).

Which hazard classes are open for commenting?

- **No current entry in Annex VI to CLP**
- **Update of an existing entry in Annex VI to CLP**

Comments during consultation

- **General comments**
- **Comments on hazard classes**

Comments supporting the proposed classification are also encouraged. Additional relevant data can also be submitted relating to the hazard classes open for comments.

Any comments arriving after the commenting deadline will not be included in the Response to Comments table, and will not be responded to by the dossier submitter and RAC.

The comments received during the consultation are available on the Registry of CLH intentions until outcome.

- Harmonised Classification and Labelling (explains the various steps of the process)
- Previous consultations
- Registry of CLH intentions until outcome

**Consultations close at 23:59 Helsinki time (EET)**

Substance Details

| | |
|---|---|
| **Name** | Glyphosate |
| **EC Number** | 213-997-4 |
| **CAS Number** | 1071-83-6 |
| **Dossier submitter** | Sweden |
| **CLP Annex VI Index Number** | 607-315-00-8 |
| **Current entry in Annex VI of CLP Regulation** | Eye Dam. 1, H318,<br>Aquatic Chronic 2, H411 |
| **Proposed future entry in Annex VI of CLP Regulation by the dossier submitter** | Eye Dam. 1, H318,<br>Aquatic Chronic 2, H411 |
| **Hazard classes open for commenting** | Physical hazards (solid substance);<br>Health hazards except respiratory sensitisation and aspiration hazard;<br>Environmental hazards |
| **CLH report** | |
| **Annexes to the CLH report** | [ZIP] Annex B2, 14Mb<br>[ZIP] Annex B6 part 1/2, 40Mb<br>[ZIP] Annex B6 part 2/2, 46Mb<br>[ZIP] Annex B8 part 1/5, 30Mb<br>[ZIP] Annex B8 part 2/5, 45Mb<br>[ZIP] Annex B8 part 3/5, 48Mb<br>[ZIP] Annex B8 part 4/5, 46Mb<br>[ZIP] Annex B8 part 5/5, 21Mb<br>[ZIP] Annex B9, 31Mb |
| **Start of consultation** | 23/09/2021 |
| **Deadline for commenting** | 22/11/2021 |
| **Consultation on CLH report** | **Give Comments** |
| **Other consultations** | A parallel consultation on the Assessment Report for glyphosate as PPP active substance is ongoing on the EFSA website (https://connect.efsa.europa.eu/RM/s/publicconsultation). Comments related to the CLH proposal should be provided to ECHA and those related to the Assessment Report to EFSA. |
| **Link to Registry of CLH intentions until outcome** | **Link** |

# *EFSA: A submission requires deep knowledge + time*

The form for submissions and the size of the Renewal Assessment Report (link)

Public Consultation
PC-0088

Title
Assessment Report on the active substance Glyphosate

Status
Open

Full Name
Assessment Report on the active substance Glyphosate

Link To Document

Public Consultation Details

Food Domain
Pesticides Peer Review (AIR)

Start Date
23/09/2021

End Date
22/11/2021

For Support Information please click here.

| Title | File Type |
| --- | --- |
| Glyphosate | ZIP |

- Glyphosate_RAR_01_Volume_1_2021-08-10.pdf
- Glyphosate_RAR_02_Volume_1_2.10.2_ED_2021-08-10.pdf
- Glyphosate_RAR_03_Volume_2_2021-08-10.pdf
- Glyphosate_RAR_04_Volume_3CA_B-1_2021-08-10.pdf
- Glyphosate_RAR_05_Volume_3CA_B-2_2021-08-10.pdf
- Glyphosate_RAR_06_Volume_3CA_B-3_2021-08-10.pdf
- Glyphosate_RAR_07_Volume_3CA_B-4_2021-08-10.pdf
- Glyphosate_RAR_08_Volume_3CA_B-5_2021-08-10.pdf
- Glyphosate_RAR_09_Volume_3CA_B-6.1-B-6.2_2021-08-10.pdf
- Glyphosate_RAR_10_Volume_3CA_B-6.3_2021-08-10.pdf
- Glyphosate_RAR_11_Volume_3CA_B-6.4_2021-08-10.pdf
- Glyphosate_RAR_12_Volume_3CA_B-6.5_2021-08-10.pdf
- Glyphosate_RAR_13_Volume_3CA_B-6.6_2021-08-10.pdf
- Glyphosate_RAR_14_Volume_3CA_B-6.7 - B-6.10_2021-08-10.pdf
- Glyphosate_RAR_15_Volume_3CA_B 7.1 - B-7.4_2021-08-10.pdf
- Glyphosate_RAR_16_Volume_3CA_B-7.5 - B-7.8_2021-08-10.pdf
- Glyphosate_RAR_17_Volume_3CA_B-8_2021-08-10.pdf
- Glyphosate_RAR_18_Volume_3CA_B-8_8.5. Monitoring data_2021-08-10.pdf
- Glyphosate_RAR_19_Volume_3CA_B-9_2021-08-10.pdf
- Glyphosate_RAR_20_Volume_3CA_B-9_Appendix literature search_2021-08-10.pdf
- Glyphosate_RAR_21_Volume_3CP_MON 52276_B-1_2021-08-10.pdf
- Glyphosate_RAR_22_Volume_3CP_MON 52276_B-2_2021-08-10.pdf
- Glyphosate_RAR_23_Volume_3CP_MON 52276_B-3_2021-08-10.pdf
- Glyphosate_RAR_24_Volume_3CP_MON 52276_B-4_2021-08-10.pdf
- Glyphosate_RAR_25_Volume_3CP_MON 52276_B-5_2021-08-10.pdf
- Glyphosate_RAR_26_Volume_3CP_MON 52276_B-6_2021-08-10.pdf
- Glyphosate_RAR_27_Volume_3CP_MON 52276_B-7_2021-08-10.pdf
- Glyphosate_RAR_28_Volume_3CP_MON 52276_B-8_2021-08-10.pdf
- Glyphosate_RAR_29_Volume_3CP_MON 52276_B-9_2021-08-10.pdf
- Glyphosate_RAR_30_Volume_3CP_MON 52276_B-9_App_lit_biodiv_2021-08-10.pdf
- Glyphosate_RAR_40_List of Endpoints_2021-08-10.pdf
- Glyphosate_RAR_Animal model 2017_2021-08-10.xls
- Glyphosate_RAR_Appendix E_ecotox_2021-08-10.xlsm
- Glyphosate_RAR_Appendix E_tox_2021-08-10.xlsm
- Glyphosate_RAR_Appendix G_2021-08-10.xlsx
- Glyphosate_RAR_EFSA primo rev3.1_2021-08-10.xlsm

# *EFSA: Submissions need to follow instructions*

Reduces the amount of superficial commentary and encourages high-quality comments

Comments will not be considered if they:

- are submitted after the closing date of the consultation;
- are still in 'draft' status on the closing date of the consultation;
- are presented in any form other than what is provided for in the instructions and the relevant function in the tool (e.g. comments made by email will not be considered);
- are made outside the corresponding fields of the form, for instance as part of supporting files uploaded in the tool;
- are not related to the contents of the document or scope of the consultation;
- contain complaints against institutions, personal accusations, irrelevant or offensive statements or material;
- are related to policy or risk management aspects, which are out of the scope of EFSA's activity.

Comments will be assessed in line with the criteria above and taken into consideration if found to be relevant.

Source: EFSA's description of „Scope of Consultation" (link)

# *EFSA: Issue matter for commentary is pre-defined*

This encourages submission of technical content by issue experts

Disclaimer

Please note the the max number of characters allowed per section is 2000. Also it is only allowed to upload one file per section with a max size of 25 MB.

> 1 Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

v 2 Effects on human and animal health

It is not possible to leave comments on this section.

> 2.01 Absorption, distribution, metabolism and excretion in mammals

> 2.02 Acute toxicity

> 2.03 Short-term toxicity

> 2.04 Genotoxicity

v 2.05 Long-term toxicity and carcinogenicity

Comments for 2.05 Long-term toxicity and carcinogenicity

Comment submitters need to select a specific data point for their commentary.

# *EFSA: Comments must refer to the specific section of the Assessment Report*

This requires a deeper understanding of the Assessment Report.

Scope of Consultation

EFSA's Pesticides Peer Review Unit has launched an open consultation on the active substance Glyphosate to gather comments on the Rapporteur Member State's Assessment Report.

A parallel consultation on CLH proposal is ongoing on the ECHA website (**https://echa.europa.eu/consultations/current**). Comments related to the CLH report should be submitted directly to ECHA.

Interested parties are invited to submit their comments by the indicated deadline. At the beginning of each comment, the reference to the assessment report corresponding to the comment should be given by indicating the Volume number, the chapter number and a short description following this structure: e.g. "Vol. 3, B.8.1, Route and rate of degradation".

Examples:
"Vol. 3, B.6.1.2 through B.6.1.4, Absorption, excretion and distribution studies. Justification for the adequacy of the use of a single radiolabel in these studies may be necessary."
"Vol. 3, B.7.1.2, Proposed MRLs. It is considered that MRLs should not be proposed for non-cereal food crops or poultry products (as intakes in poultry are not significant)."

# *EFSA: Comments and attachments need to be copy-right cleared*

EFSA will publish all comments including third-party content that is referenced in submissions

Copyright-cleared contributions:
Persons or organizations participating in a public consultation of EFSA are responsible for ensuring that they hold all the rights necessary for their submissions and subsequent publication by EFSA. Comments should inter alia be copyright-cleared considering EFSA's transparency policy and practice to publish all submissions. In case the submission reproduces third-party content in the form of charts, graphs or images, the required prior permissions of the right holder(s) should have been obtained by the public consultation respondent.

Publication of contributions:
Third-party comments will be made public in their original form without delay after the closing date of the consultation and may be reused by EFSA in a different context. The outcome of the consultation will be made public in conjunction with the publication of the relevant scientific output.

Contributions submitted by individuals in a personal capacity will be published indicating the author's first and family name, unless the respondent has requested anonymity.

Contributions submitted on behalf of an organisation will be attributed to the organization in question.

# ECHA

# Hazard assessment and classification

# Regulation (EC) No 1272/2008

*/// EU Public Commenting Period /// September 2021*


Glyphosate Renewal Group

# *ECHA: Issue matter for commentary is pre-defined*

Submissions require a deeper understanding of the subject matter. Link to ECHA commenting-page on dossier proposing harmonised classification and labelling of glyphosate (link)

Comments

ECHA accepts no responsibility or liability with regard to the information (including attachments) submitted through the webform.

**Instructions:**

1. **Comments submitted through this webform should be non-confidential and will be published on ECHA's website.** Non-confidential attachments are also published on ECHA's website.
2. **Do not submit attachments without highlighting the relevance of the attached document in the commenting box.** Attachments sent without an accompanying comment may not be possible to take into account.
3. If you submit a confidential attachment, please also provide a version with confidential parts removed/blanked out, which will be published on ECHA's website.
4. Umbrella organisations are recommended to submit one set of comments/attachments during the consultation phase on behalf of the member companies/organisations, rather than individual companies/organisations submitting the same comments separately.
5. **Please submit comments/information on the hazard classes open for consultation as indicated on ECHA's website, and in the commenting fields below.** In developing its opinion, RAC may consider another category more appropriate for the classification of the substance after examining the available information in the CLH report, its annexes and information received during the consultation. You are therefore encouraged to also give support for a proposal you agree to. Arguments on why a higher or lower classification is or is not appropriate are appreciated.
6. **Results of toxicological and ecotoxicological studies, and other information listed in Article 119 of the REACH Regulation, as read together with Article 10(2) of the CLP Regulation, cannot be claimed confidential.** Information claimed confidential not in line with these provisions may not be taken into account if the confidentiality claim prevents the publication of the justification of the opinion.
7. **The CLH report will not be updated following the consultation.** Therefore, comments related to language, typographical errors or editorial changes to the text of the report may not be relevant.

* ☐ I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, email addresses, phone numbers, signatures etc). ECHA will not be held liable for any damages caused by making non confidential responses publicly available.

**General Comments - use this field for non-hazard class related comments**

Where relevant, please add the reference to the page or section of the CLH report your comment refers to

**Comments on the open hazard classes:**

Carcinogenicity:

Mutagenicity:

Reproductive toxicity:

Physical hazards:

Acute toxicity:

Skin corrosion/irritation:

Serious eye damage/eye irritation:

Skin sensitization:

Specific target organ toxicity – single exposure:

Specific target organ toxicity – repeated exposure:

Hazardous to the aquatic environment:

Hazardous for the ozone layer:

# *ECHA: Submission of supporting material permitted*

Relevance of supporting material has to be justified and referred to in commentary

**Public attachment**

Upload Attachment:

This information can be made publicly available. Please highlight the relevance of the attached document and the supportlive information in the comment boxes above.

Add attachment | Browse

*Maximum file size is 10 MB*

*If you would like to submit more than one document, please create a zip archive where you include all files and upload the zip file as attachment. Maximum file size is 10 MB.*

* ☐ I have removed/blanked the information I want to keep/I have claimed confidential from all the attachments (for example: company name, company logo, if claimed confidential, personal data, signatures, and confidential business data). I have also highlighted the relevance of the attached document in the commenting box. I understand that ECHA will not be held liable for any damages caused by making the attachments publicly available.

**Confidential attachement**

Upload Attachment:

This information will only be made available to the Member State competent authority submitting the CLH dossier, ECHA, its Committees and the European Commission. If the dossier submitter is a manufacturer, importer or downstream user, confidential information will not be provided to them.

Add attachment | Browse

*Maximum file size is 10 MB*

*If you would like to submit more than one document, please create a zip archive where you include all files and upload the zip file as attachment. Maximum file size is 10 MB.*

* ☐ I have provided a non-confidential version which may be published on ECHA's website. Results of toxicological and ecotoxicological studies, and other information listed in Article 119 of the REACH Regulation, as read together with Article 38(2) of the CLP Regulation, cannot be claimed confidential. Information claimed confidential not in line with these provisions may not be taken into account if the confidentially claim prevents the publication of the justification of the opinion.

# *ECHA: Attachments without comments may not be taken into account*

Reduces the impact of superficial commentary and encourages high-quality comments

### Comments

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# *Summary*

- Submitters of commentary need to fill out a pre-defined form and select the subject matter they want to comment upon.
- Submitters of commentary need a deeper understanding of the dossier and science.

**Comments will not be considered if they:**

- Are not related to the contents of the document or scope of the consultation;
- Contain complaints against institutions, personal accusations, irrelevant or offensive statements or material;
- Are related to **policy or risk management aspects**, which are out of the scope of EFSA's activity.