

THE GLOBAL POSITION FOR GLYPHOSATE – IS IT IMPROVING?

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Agenda/Topics

- Background
- EU Renewal
 - Timeline; Extension vote; Key technical topics; Peer review expert meetings
- GB Renewal
- US Litigation
- Summary

Background

- GLY-based herbicides, are a tool in Integrated Weed Management, providing efficient and cost-effective weed control for more than 40 years.
- Farmers who apply GLY have greater success in the fight against weeds, while those who do not can experience harvest losses of up to 22 percent.
- GLY is an important tool in Genetically modified crops, by allowing farmers to use the herbicide in a way that eliminates weeds without harming desirable plants.
- GLY-tolerant crops and GLY-based herbicides are a major enabler of no-till and reduced tillage farming practices, thus reducing carbon emissions.
- GLY is the most studied herbicide in the world and is subject to rigorous testing and oversight by regulatory authorities. There is an extensive body of research on glyphosate including more than 800 scientific studies submitted to worldwide regulators as part of the registration process. These confirm that it can be used safely and does not cause cancer.
- Leading regulators around the world have repeatedly concluded that GLY products can be used safely, and that it is not carcinogenic. This includes recent conclusions by the US EPA, the EU Assessment Group on Glyphosate (AGG), EFSA and ECHA, and many more. The only opinion outside of this conclusion is the IARC opinion of 2015 that it “is probably carcinogenic to humans”.

Glyphosate EU Renewal

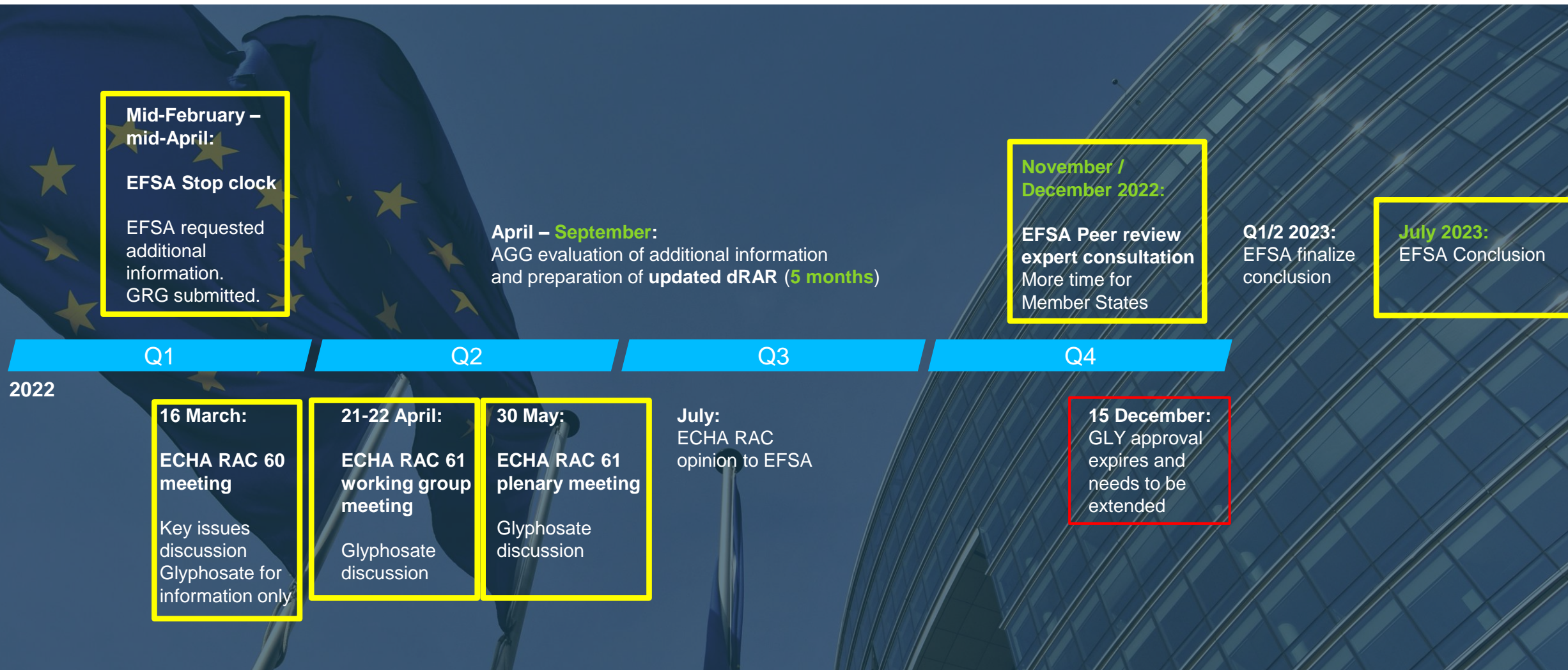
- AIR granted 15/12/2017 for 5Y (even CfS given 7Y, usually 15Y)
- Current EU Expiry date = 15 December 2022
- AGG evaluation complete, Peer review process to start
- Evaluation process incomplete due to authority delays
- SCoPAFF Extension voted took place on 14 Oct 2022
 - Need for 15 MS and 65% of total population to carry Commission proposal to extend expiry
 - 21 MS +ve; 3 MS -ve (small countries) and 2 Abstentions (Germany and France)
 - 64.73% of population
- Appeal Committee on Phyto-pharmaceuticals on 15 Nov 2022
 - If no majority, then Commission proposal for extension should stand
- Expectation that will be an extension of 1 year to 15 December 2023



Glyphosate EU Renewal Next Steps: EFSA / ECHA Timeline – 2022



Renewal process will be delayed until *at least* end 2023 – going beyond the current GLY approval period
 Timeline updates in **green** according to latest [EFSA/ECHA communication](#) on updated timelines



Revised dRAR – Key Technical Topics



■ Toxicology

- No critical areas of concern regarding Toxicology
- Increases in ADI, AOEL and ARfD proposed

■ E-fate

- No Issues that could not be finalised or critical areas of concern regarding Environmental Fate
- All PECgw estimates were below 0.1 µg/L for intended uses

■ Ecotox

- No Issues that could not be finalised or critical areas of concern regarding Ecotox

■ Residues


- No Issues that could not be finalised or critical areas of concern regarding residues
- Owing to the large margin of safety all representative uses (including those in non-permanent crops) may be considered safe for consumers

EFSA Pesticide Peer Review Experts' Teleconferences on Glyphosate


- EFSA website contains dates and draft discussion points for glyphosate expert calls:

[Plant Protection Products and their Residues | EFSA \(europa.eu\)](#)

Dates and draft discussion points

[Pesticide Peer Review planned meetings 2022](#) 

2022 meetings:


- [Pesticide Peer Review Experts' Teleconferences November-December 2022](#) 

- 14 November – 25 November → Glyphosate **mammalian toxicology**
- 14 November – 25 November → Glyphosate **fate and behaviour**
- 21 November – 2 December → Glyphosate **ecotoxicology**
- 28 November – 2 December → Glyphosate **residues**
- 1 December – 2 December → Glyphosate mammalian toxicology – ecotoxicology joint session on **ED properties**

EFSA Pesticide Peer Review Experts' Teleconferences on Glyphosate

- TWGs prepared **scientific summary documents**, highlighting GRG's position on key aspects
- Summary docs are
 - placed on GRG website ("Transparency" => "Scientific Dossier" => "GRG Position on Scientific Topics")
 - **distributed to Member State regulatory authorities** for their information/consideration

Key aspects of the information that GRG submitted to address EFSA's request for additional information in the frame of EU glyphosate active ingredient approval renewal, according to Regulation (EC) No 1107/2009



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Regulation (EC) No 1107 /2009,
EFSA request for additional
information

DOC ID: 113898-280
DATE: 13 October 2022

Key aspects in the area of environmental fate

- Assessment of pH dependency and consequences for endpoint selection
- Conclusion on representativeness of US field data for the EU – Ecoregion crosswalk
- Unknown radioactivity in AMPA-applied water-sediment studies
- Monitoring data


Glyphosate Renewal Group
Key aspects in the area of environmental fate



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GB Renewal Process




- NI = continues to follow EU
- GB = Automatic extension for all AS expiring in 2021, 22 & 23 at Brexit, to allow establishment of a GB Renewal Programme
 - Current GB Glyphosate expiry = 15/12/2025
 - No GB renewal programme yet; wide acknowledgment that expiry dates will have to be extended
 - GB review of major -ve decisions elsewhere; “GB makes its own decisions”
 - Await data requirements and process
- GB review of MRL’s and IT’s planned for 2023; No expected impact on trade


US Litigation Update





- The ongoing litigation in the US primarily stems from one place: the IARC opinion classifying GLY as a 'probable carcinogen' in 2015
- Following this, US trial attorneys began running adverts to recruit plaintiffs for lawsuits against Monsanto, and its GLY-based herbicides (i.e., Roundup™-branded herbicides). These lawsuits rely heavily on IARC's classification.
- On August 10, 2018, a jury in Johnson v. Monsanto, found Monsanto liable for Mr. Johnson's non-Hodgkin's lymphoma. The judge later reduced the damages from \$289M to \$78M. After much legal wrangling, on October 21, 2020, the California Supreme Court denied Monsanto's petition for review. 2 further cases were found in favour of plaintiffs over 2019-2021 and petitions for review denied
- On October 5, 2021, the first case found in favour of Monsanto/Bayer and there have now been a total of 5 cases in favour of Monsanto/Bayer. There are 2 further trials ongoing.
- While we have great sympathy for the plaintiffs, the jury weighed the evidence from both sides and concluded that Roundup™ is not responsible for their injuries.
- Bayer will vigorously defend its products based on the strong body of science that confirms glyphosate and glyphosate-based products are safe when used as directed and that glyphosate does not cause cancer.


Bayer published a five-point plan in May 2021, which provides a clear path to closure of the U.S. glyphosate litigation.

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- 1. Seek positive ruling from the U.S. Supreme Court: 

 - 2. Activate claims program to manage future cases: 

 - 3. Continue to manage current cases: 

 - 4. Introduce new U.S. Lawn & Garden (L&G) formulations: 

 - 5. Promote new safety study webpage: 



Summary

- EU renewal = +ve so far; need for extension of expiry
- GB renewal = expected extension; await requirements
- Toxicology = Clean bill of health worldwide, except for IARC 2015
- All information widely available via transparency websites
 - <https://www.glyphosate.eu/transparency/>
 - <https://www.bayer.com/en/glyphosate/glyphosate-roundup>
- Remains an important tool for sustainable agriculture

THANK YOU!



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