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# Update on the glyphosate renewal peer review process

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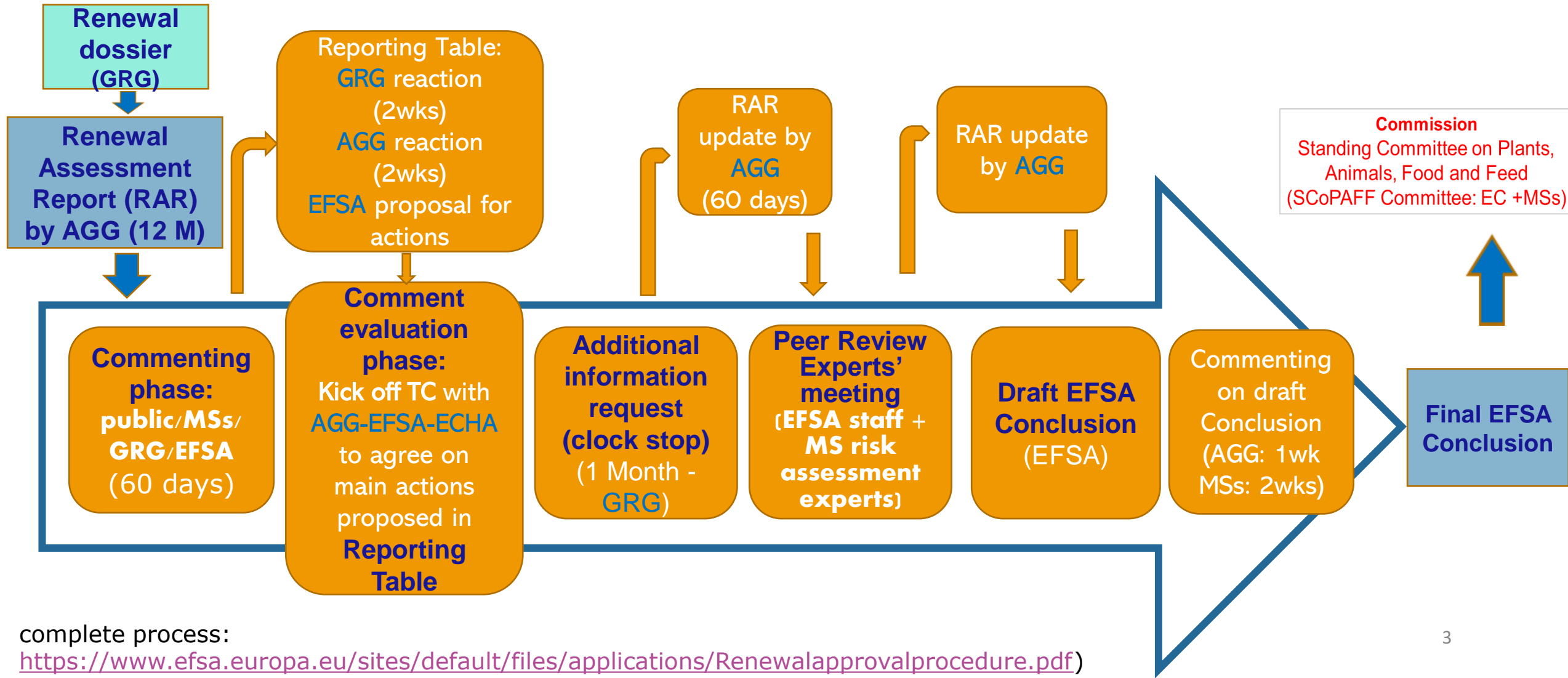
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## Overall background

- Current approval of glyphosate expires in **Dec 2022**
- Applicant: **Glyphosate Renewal Group (GRG)**
- RMS: consortium of 4 MSs (France, Sweden, Netherlands, Hungary) - **Assessment Group of Glyphosate (AGG)**
- Legal basis: Renewal under **Regulation 844/2012** => **new transparency provisions not applicable**
- **Close collaboration between EFSA-ECHA along the whole peer-review process** to avoid discrepancy in RA
  - ECHA classification process run in parallel
  - ECHA RAC Opinion expected 'on time' for EFSA
  - Joint public consultation, data sharing and meetings for alignment between EFSA-ECHA-AGG-SANTE

# UPDATE ON THE GLYPHOSATE PEER REVIEW PROCESS

## EFSA peer review process



complete process:

<https://www.efsa.europa.eu/sites/default/files/applications/Renewalapprovalprocedure.pdf>

**Renewal dossier 2020 and RAR 2021 = a significant amount of information and data to be processed**

## **Renewal dossier 2020**

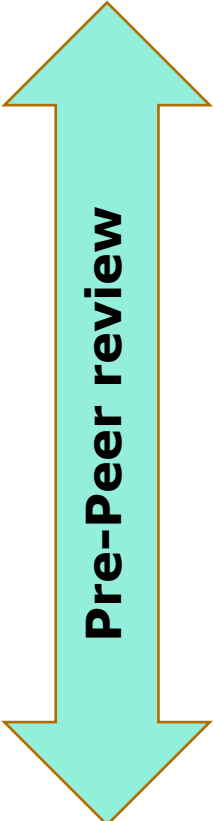
- ca **180,000 pages** or 2-4 times more information than a 'standard' renewal dossier
- approximately **1,500 scientific studies**, out of which  $\sim >100$  are new
- around **12,000 published scientific peer-reviewed articles** published within the last 10 years

## **RAR 2021**

- **>11 000 pages** (e.g. 4000 pages/tox; 1900 pages/ecotox)

Both sanitised **summary dossier** and **non confidential version of RAR** are available [Open EFSA](#) (see EFSA-Q-2020-00140: 'Evidences Inventory') and [Open EFSA public consultation page](#), respectively.

## Timelines – what happened so far



<b>Sept–Oct 2019</b>	<b>Pre-submission meetings between AGG/GRG + EFSA as observer</b>
<b>15 Dec 2019</b>	<b>Application for the renewal of the active substance glyphosate submitted by the GRG (3 yrs before expiry of approval)</b>
<b>31 Jan 2020</b>	<b>Declaration of completeness of the application by AGG</b>
<b>8 June 2020</b>	<b>Renewal dossier submitted by GRG to AGG members (FR, NL, SE, HU)</b>
<b>18 Aug 2020</b>	<b>Confirmation of admissibility of revised renewal dossier of July 2020 by AGG</b>
<b>15 June 2021</b>	<b>Combined RAR/CLH report submitted by AGG to EFSA/ECHA</b>
<b>mid June-mid Aug 2021</b>	<b>EFSA Completeness Check (CC) (APDESK) // ECHA Accordance Check (AC)</b>
<b>by 17 Sept 2021</b>	<b>Sanitization exercise of combined RAR/CLH-report completed</b>

## What's ongoing?

- Ongoing **public consultation** EFSA\_ECHA (deadline: 22 November 2021)
- Targeted consultation on RAR with MSs/GRG/EFSA
- Establishment of a **dedicated 'WG on Glyphosate Peer Review-Renewal Assessment'** to support to EFSA units involved in the peer-review process

## What comes next?

- Evaluation of comments
  - Applicant (GRG) and AGG will be asked to answer all comments (including from MSs and EFSA). Feedback to EFSA and ECHA expected by **mid January 2022**.
- If needed, request for additional information following clock-stop rules
  - Subsequent update of RAR
- Peer-review experts' meetings
- Draft EFSA conclusion
- MSs commenting on draft conclusion
- Final conclusion expected **by 2<sup>nd</sup> half of 2022**

- Getting prepared for the next challenges:
  - High public scrutiny expected not only for toxicological risk assessment but also on the environmental dimension
  - Increased media attention

## EFSA **team** with role of **bridging science, institutional relations** and **communication** :

- Coordinate with AGG, ECHA, SANTE external comms and overall comms approaches;
- Gather intelligence on the debate around glyphosate;
- Inform partners, interested parties and the public about the re-assessment process.



## Milestones:

- 2 joint EFSA/ECHA press releases;
- Joint Twitter promotion of the ongoing Public Consultation;
- EFSA/ECHA alignment on external enquiries;
- Engagement with NGOs representatives;
- EFSA's media and social media monitoring newsletter (bi-weekly) – shared with staff and partners;
- Glyphosate [topic page](#) always updated;
- Updates to Communication Experts Network (CEN) on state of play via online shared space.

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