



81st Advisory Forum meeting
Virtual meeting, 27-28 October 2021

Update on the glyphosate renewal peer review process

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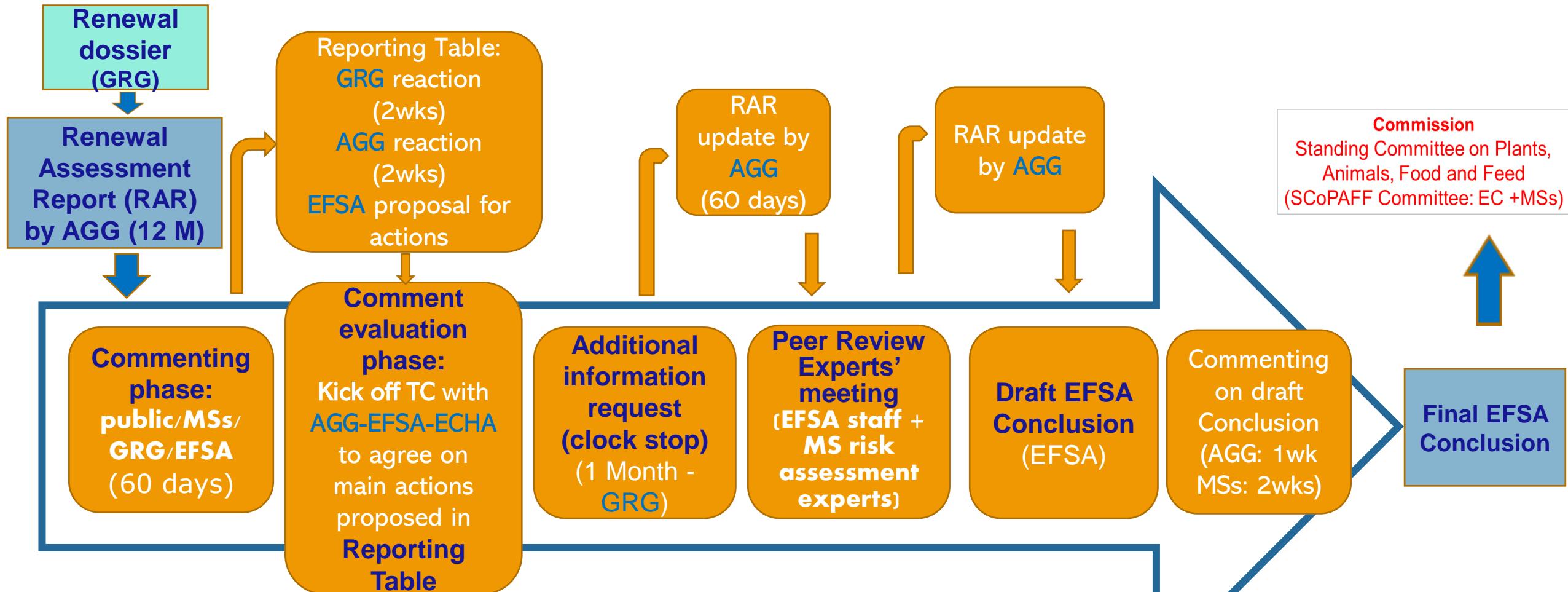
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Overall background

- 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

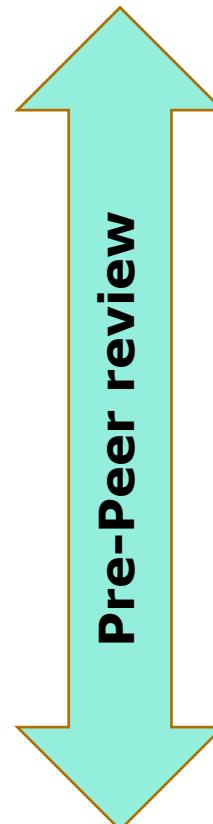
- ca **180,000 pages** or 2-4 times more information than a 'standard' renewal dossier
- approximately **1,500 scientific studies**, out of which ~>100 are new
- around **12,000 published scientific peer-reviewed articles** published within the last 10 years

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



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

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 2nd 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.



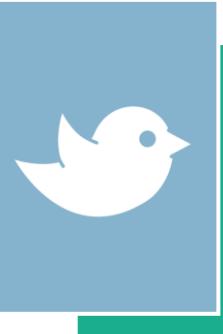
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