EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for Food Sustainability responsible for Directorates E, F and G

Brussels
SANTE/E4/MW/ai/(2023)9612331

Dear Ms Lysimachou and Ms Strobel,

Subject: Your letter of 7 September 2023 titled "Stop the reapproval of glyphosate due to major deficiencies in carcinogenicity assessment"

I refer to the above-mentioned letter (registered under our ref: ARES(2023)6078700) sent to Commissioner Kyriakides, in which you express concerns on behalf of 15 European civil society organisations about the assessment of carcinogenicity carried out as part of the recent renewal assessment of glyphosate. Commissioner Kyriakides asked me to respond on her behalf.

Since most of the points raised in the letter are of technical and scientific nature, I have asked the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) to consider your letter and provide a statement thereon by 6 October 2023 at the latest, in particular on whether the aspects raised have any impact on the overall assessment and conclusions adopted by EFSA and ECHA.

Nevertheless, I would like to respond to the claims that the procedure is being rushed and the accusation that the interest of industry is taking priority over the protection of health and the environment.

I would like to recall that as for any active substance the Commission is committed to ensuring that the decision on (renewal of) approval is based on science and in line with the provisions of EU law.

It is important to also recall that specific rules are laid down for the renewal of approval of active substances used in plant protection products, in the case of glyphosate those set

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out in Regulation (EU) No 844/2012. Those rules have been and continue to be followed. The procedure includes a public consultation on the assessment carried out by the rapporteur Member States (in the case of glyphosate the Assessment Group on Glyphosate). The comments made by NGOs and citizens were considered as part of the peer review process. Furthermore, the process of harmonised classification and labelling managed by ECHA includes a public consultation and enables participation during the meetings of the Risk Assessment Committee; according to minutes of RAC-60 and RAC-61 two NGO observers, Client Earth and HEAL, made presentations putting forward their positions and participated in the discussion on carcinogenicity. Therefore, there were ample opportunities for NGOs and others to express views that were then considered as part of the scientific discussions and conclusion reached.

Once EFSA made available its Conclusion in July 2023 the standard steps were undertaken i.e. discussions were initiated with Member States in the Standing Committee on Plants, Animals, Food and Feed, and a draft Renewal Report was made available to Member States for commenting. Information on this part of the process was also added to the Commission's glyphosate webpage ([1]) to ensure full transparency in view of the particularly high interest from civil society.

EFSA also maintains a dedicated updated webpage ([2]) where it provided an overview of the conclusion once it was transmitted to Member States and the Commission, and where it published the full Conclusion swiftly thereafter following the process required by Regulation (EU) No 844/2012. The accompanying Peer Review Report and the final version of the Renewal Assessment Report have also been published allowing interested parties to understand the peer review process and the conclusions reached.

The Commission services initiated discussions with the Member States in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) of 12 July 2023 – a summary of those discussions was published ([3]). The Commission services submitted a draft Renewal Report to Member States on 13 July 2023 for their consideration and comments.

The Commission services have carefully examined comments received by Member States in view of further discussions in the Standing Committee meeting planned for 22 September 2023 ([4]). A draft Regulation and an updated Renewal Report have been published in the Comitology Register ([5]) as per standard procedure, as well as on our glyphosate webpage.

([1]) https://food.ec.europa.eu/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en

([2]) https://www.efsa.europa.eu/en/topics/topic/glyphosate

([3]) https://food.ec.europa.eu/system/files/2023-08/sc_phyto_20230711_ppl_sum-glyphosate.pdf

([4]) https://food.ec.europa.eu/document/download/c60e5e91-0f89-4b14-9ae2-02b52386bc66_en?filename=sc_phyto_20230922_ppl_agenda.pdf

([5]) https://ec.europa.eu/transparency/comitology-register/screen/meetings/CMTD%282023%291319/consult?lang=en

Let me conclude by noting that the time schedule followed for the upcoming decision has been established in view of concluding the decision-making process prior to the expiry of the current approval and to avoid the need for a further extension in accordance with Article 17 of Regulation (EC) 1107/2009. Your organisations have repeatedly criticised the Commission for extending approvals due to delays in the scientific evaluation or in the decision-making process for the renewal of approval of active substances and as you are certainly aware, an NGO from Germany has requested a review under the Aarhus Regulation of the extension of the approval of glyphosate that became necessary due to the delays in the scientific evaluation.

I confirm that the letter has been shared with Member States ahead of the meeting of the PAFF Committee on 22 September 2023.

Yours sincerely,

Claire BURY

Cc: Ms M. Tiramani, Ms T. Molnar (EFSA)
Mr P. Ryan, Mr. A. Karjalainen (ECHA)
Mr K. Berend, Ms A. Tuijtelaars, Ms A. Bitterhof, Ms K. Nienstedt, Mr N. Tzvetkov, Mr M. Williams (DG SANTE)