EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
Pesticides and Biocides

Brussels,
SANTE/E4/NT/gb(2024)2070404

Dear Mr Patten,

Subject: Your mail dated 8 November 2023 on the renewal of glyphosate in the European Union

Thank you for your letter (registered under our ref: ARES(2023)7615294) sent to Mr Klaus Berend, who asked me to reply on his behalf.

I can assure you that the protection of human health and environment are highest priorities of the European Commission. The EU legislation on pesticides is among the strictest in the world. Active substances can only be approved for use in plant protection products when it has been demonstrated that they can be used in a way that they have no harmful effects on human health or unacceptable effects on the environment while being efficient. This includes adverse effects on the nervous system, including neurodegenerative diseases and conditions.

While I fully understand your concerns, I would also like to emphasise that evidence-based regulatory decision making is very important to the Commission. The risk assessment conducted in the context of the renewal process of glyphosate and summarised in the EFSA Conclusion ([1]) is based on an unprecedented amount of scientific information including both regulatory studies and peer-reviewed publications. Specifically with respect to the Parkinson's disease, the Conclusion noted that "*the integration of human observational studies with the limited experimental evidence from in vitro and in vivo studies does not trigger a concern for parkinsonism*." (see last paragraph on page 20 of the Conclusion).

EFSA did not identify any critical areas of concern that would preclude the renewal of the approval of glyphosate for use in plant protection products. It did identify some data gaps and could not fully finalise the assessment of some issues, however such are identified for almost all active substances. It is precisely the role of the Commission and Member States as risk managers to consider the specific gaps and how these impact the overall conclusion on safety and then to set conditions and restrictions to manage any possible uncertainties or risks.

([1]) https://www.efsa.europa.eu/en/efsajournal/pub/8164

Mr Russell Patten
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The Commission discussed the open points with Member States between July and October 2023 in the Standing Committee on Plants, Animals, Food and Feed (PAFF) and concluded that they could be satisfactorily addressed through appropriate conditions in the renewed approval for the reasons set out in detail in the Renewal Report on glyphosate ([2]). The Commission presented a draft Implementing Regulation for renewal of approval for a period of 10 years, subject to certain conditions.

During the meeting of the PAFF on 12-13 October 2023, the vote by Member States on the draft Implementing Regulation to renew the approval of glyphosate led to no qualified majority neither in favour nor against the Commission's proposal. Therefore, the draft Regulation was referred to the Appeal Committee, held on 16 November 2023, which delivered the same outcome (no opinion). Subsequently, on 28 November 2023, the European Commission adopted the Implementing Regulation to renew, for 10 years, the approval of glyphosate. The Implementing Regulation ([3]) was published in the Official Journal of the EU on 29 November 2023.

Let me also underline that Member States can authorise products containing glyphosate only when it is clearly demonstrated by a further assessment which takes into consideration the conditions set in the renewed approval and the specific circumstances in their territories, that the use of those products does not cause harmful effects on health and does not pose unacceptable risks to the environment. Member States should monitor whether the assumptions made during the authorisations are met during the actual use and if necessary, amend or even withdraw authorisations when they detect that these are not implemented correctly.

Please also note that if new data become available that provide indications that the approval conditions are no longer met, the Commission can initiate a review of the approval at any time and amend or withdraw it, if necessary, as it has done in the past for other substances. This includes new data on the nervous system, including new data linked to the Parkinson's disease, which as an active area of research ([4]).

You can find further information on the Commission's glyphosate webpage ([5]) as well as on the EFSA ([6]) and ECHA ([7]) webpages.

Yours sincerely,

Eric Thévenard
Head of Unit

([2]) https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/backend/api/active_substance/download/1424

([3]) Commission Implementing Regulation (EU) 2023/2660 of 28 November 2023 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L, 2023/2660, 29.11.2023)

([4]) Bloem, B.R., Boonstra, T.A., Elbaz, A. et al. Glyphosate and neurotoxicity — a call for scientific renewal. Nat Rev Neurol (2024). https://doi.org/10.1038/s41582-023-00919-7

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

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

([7]) https://echa.europa.eu/de/substance-information/-/substanceinfo/100.012.726