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Brussels, 15 November 2021

Dear Ms Jensen,

Thank you for your letter dated 13 October 2021 sent on behalf of HEAL and 40 other civil society organisations in which you express concerns about the ongoing renewal assessment process for glyphosate, in particular concerning the credibility of the studies that have been provided by the applicant, the Glyphosate Renewal Group (GRG), in its renewal dossier.

I first would like to recall that as part of EU safety assessments for active substances used in plant protection products, all available information must be taken into consideration to ensure rigorous and scientifically robust assessments. Active substances are periodically reviewed so that advances in scientific and technical knowledge are taken into account. Assessments are based on studies that applicants submit to fulfil specific data requirements set out in the legislation, which are carried out in laboratories that must be certified to work in accordance with Good Laboratory Practice and according to internationally recognised protocols and test guidelines, as well as all relevant available scientific peer-reviewed open literature. Independent and objective assessments are carried out by the Rapporteur Member States in the light of current scientific and technical knowledge using guidance documents applicable at the time of submission. The European Food Safety Authority (EFSA) ensures that assessments are subject to public consultation and peer reviewed by experts from all Member States and, where relevant, experts from EFSA's scientific panels and working groups.

Active substances used in plant protection products are subject to harmonised classification and labelling in accordance with the Regulation on the classification, labelling and packaging of chemicals. Proposals for harmonised classification and labelling (which includes hazard classes related to human health (including carcinogenicity) and the environment) have to be submitted by the Rapporteur Member States to the European Chemicals Agency (ECHA). ECHA ensures that classification proposals are subject to public consultation before the

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Committee for Risk Assessment (RAC) delivers its opinion on the classification of the substance.

Results from scientific studies do not become invalid per se over time. However, the utility of studies and their results for risk assessment may change over time based on the evolution of scientific and technical knowledge. During the risk assessments conducted by the Rapporteur Member States and the peer review process overseen by EFSA, all studies are considered for their reliability and relevance. I can confirm that all data is considered at renewal, both old and new.

As part of the assessment of an active substance, at least one representative use of at least one plant protection product containing the active substance must be considered. Tests are provided on the active substance and, where so required, the formulated product in order to allow for an assessment of the impacts on human and animal health and the environment. The co-formulants contained within the product are also considered. At EU-level, the Commission already took action in 2016 to ban the use of POE-tallowamine in plant protection products containing glyphosate due to concerns about its impact on human health and in 2021 adopted a list of unacceptable co-formulants including POE-tallowamine (Annex III to Regulation EC No 1107/2009), which cannot be used in any plant protection product, to further strengthen safety.

Importantly, I also recall that in addition to the assessment in the context of the procedure for renewal of approval of an active substance, Member States must conduct an assessment for each plant protection product containing an approved substance before they can grant an authorisation for the placing on the market and use of the product.

As you noted in your letter, public consultations on the assessments carried out by the Member States that constitute the Assessment Group on Glyphosate (AGG) were launched by EFSA and ECHA on 23 September 2021 according to the procedures foreseen in Regulation (EU) No 844/2012 and Regulation (EC) No 1272/2008, respectively. These consultations provide a means for all interested parties to scrutinise the assessments carried out by the AGG and provide comments and scientific arguments on the evaluation of the data as well as identifying additional information to be taken into account. Therefore, I encourage you and the other organisations to submit your analysis of the credibility of the individual studies contained in the dossiers submitted by the GRG, the availability of studies on formulated products, and any other specific comments directly to EFSA and/or ECHA by 22 November 2021[1] so that they can be considered as part of the peer-review process.

In your letter, you call on the Commission to financially support the study on glyphosate being undertaken by the Ramazzini Institute. According to Article 32d of the General Food

[1] Information on the consultations including how to submit comments can be found via the following links:
https://www.efsa.europa.eu/en/news/glyphosate-efsa-and-echa-launch-consultations
https://echa.europa.eu/-/glyphosate-echa-and-efsa-launch-consultations

Law, the Commission may, in exceptional circumstances of serious controversies or conflicting results, request EFSA to commission scientific studies with the objective of verifying evidence used in its risk assessment process. Given that the peer review process for the assessment of the renewal dossier for glyphosate has only started recently – and as mentioned earlier your concerns can be addressed as part of the peer review process if all relevant information is provided during the ongoing public consultations – it seems premature to conclude at this point in time that there is a need for such verification studies.

Nevertheless, if, following the outcome of the peer-review process, exceptional circumstances of serious controversies or conflicting results emerge, the Commission would be ready to consider the possibility to conduct such verification studies, on the basis of the applicable legal framework.

Allow me also to recall that Regulation (EU) No 844/2012 governing the renewal process has established strict timelines to complete the assessment in view of the possible renewal of approval of active substances. It appears from your letter that the full study by the Ramazzini Institute will not be available to be submitted within the public consultation periods referred to above or even later in the peer review process in accordance with the timelines laid down in the Regulation – I would nevertheless invite you to submit any intermediate results, if available, during the public consultation. Your request for the results of the full study to be taken into account, let alone the possible conduct of verification studies commissioned by EFSA – if applicable – following the peer review, would mean delaying the renewal process, potentially significantly, which would require extension of the current approval.

Finally, given that the assessment of glyphosate by the AGG, EFSA and ECHA is ongoing, I encourage you to make sure all comments and views are submitted to EFSA and ECHA as part of the ongoing public consultations so that they can be fully taken into account in the peer review.

Yours sincerely,