EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
The Director

Brussels,
SANTE/E4/MW/ai(2023)11779175

Dear Ms Lysimachou,

Subject: Your letter of 27 October 2023 calling for the non-renewal of the approval of glyphosate in the European Union

I refer to your above-mentioned letter sent to Commissioner Kyriakides in which you refer to new scientific evidence on glyphosate coming from a multi-institutional study, the so called "Global Glyphosate Study" (GGS), presented by the Ramazzini Institute on 25 October 2023 ([1]). You state that the findings show that glyphosate and glyphosate-based herbicides can cause leukaemia and you therefore consider that the approval of glyphosate should not be renewed. In addition, you refer to other concerns about impacts on human health and the environment, referring to a number of published papers. Commissioner Kyriakides asked me to respond on her behalf.

First, it is important to note that, so far, the Ramazzini Institute – apart from the public announcement and a presentation at a conference - has not made available the full results or details of the long-term study performed as part of the GGS. Therefore, it is impossible for experts, including those from EFSA and ECHA, to assess the experimental design and results or provide a view on their relevance and possible impact in the context of the assessment of glyphosate carried out in the EU.

Further assessment by EFSA and ECHA of the full details and results from the GGS is required to determine whether the findings affect the existing conclusion on glyphosate. As you know, ECHA and EFSA concluded two times – in 2017 and in 2022 - that based on the available evidence and taking a weight of evidence approach, no classification for carcinogenicity is warranted for glyphosate considering the criteria set out in Regulation (EC) No 1272/2008 on the classification, labelling and packaging of chemicals (the CLP Regulation) – which applies for all chemicals in the EU. I would also like to recall that ECHA and EFSA already responded to criticism from PAN Europe and others on the assessment of carcinogenicity.

The Commission has written to ECHA and EFSA asking them to contact the Ramazzini Institute to obtain access to the full study including raw data. Once the Ramazzini Institute makes the requested information available, the agencies will review it. Please note that EFSA tried already several times during the last months to obtain data coming

([1]) Global Study Reveals Glyphosate Causes Leukemia in Early Life (glyphosatestudy.org)

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from the GGS to include it in the renewal assessment of glyphosate, but regrettably so far, the Ramazzini Institute has not responded to these requests.

In addition, the material made available so far by the Ramazzini Institute does not allow to confirm which formulation was used for the tests: although it was stated that one of the formulations tested 'Roundup BioFlow' (MON 52276) is used in the EU, it is unclear whether the product tested was obtained before or after the ban of POE-tallowamines in 2016. The other formulation tested was from the US and contained POE-tallowamines which were banned in the EU. It is essential that this information will be provided to the agencies to enable a meaningful assessment.

You also raise concerns about the assessment of the product for representative uses, mentioning a lack of long-term toxicity data on one co-formulant and on the formulation. Although EFSA set a data gap for repeated-dose toxicity information for one of the components of the product for representative uses, it is noted that the component (of one co-formulant in the product) is exempt from registration under the REACH Regulation since it is a polymer. The applicants were, therefore, not obliged to submit data on the substance in the supplementary dossiers. Moreover, neither the Assessment Group on Glyphosate nor EFSA requested additional data on the substance from the applicants during the peer review. Experts from the AGG and Member States who took part in the expert discussions agreed that the available toxicological information for the product and for the individual co-formulants is sufficient to conclude that there are no indications of concern. The co-formulant containing the particular component is present in plant protection products currently authorised by Member States and Member States confirmed that during the national assessments of the product, an assessment of the co-formulant in question was performed including physical-chemical and toxicological considerations with the conclusion that the co-formulant is not of toxicological concern. Nevertheless, please note that the importance of the assessment of co-formulants is specifically addressed in the Commission's proposal for the renewal of approval of glyphosate which obliges Member States to pay particular attention to the co-formulants present in glyphosate-containing plant protection products, taking into account the criteria for identification of unacceptable co-formulants when carrying out assessments for authorisation of products.

Regarding the other concerns raised in your letter, the possibility for glyphosate to cause human diseases was specifically considered as part of the risk assessment by Member States and EFSA. Available epidemiological studies were considered. While individual studies may show particular findings, ECHA and EFSA have reached their conclusions on the hazards and risks of glyphosate based on the weight of evidence i.e. taking all findings (positive and negative) into account.

Based on the available data there were no relevant indications of neurodegenerative changes in the available neurotoxicity studies. The peer review also concluded that the integration of human observational studies (epidemiological studies) with the limited experimental evidence from *in vitro* and *in vivo* studies does not trigger a concern for Parkinson's disease and that there is no evidence on the possible association between glyphosate exposure and autism spectrum disorder (ASD) or amyotrophic lateral sclerosis (ALS). The impact of glyphosate on the microbiome was also considered by expert in the peer review where it was concluded that the available studies on potential effects of glyphosate on the human and animal gut microbiome are not expected to impact the risk assessment, based on the current state of knowledge. A consideration of the impact on the microbiome of non-target organisms was also performed.

Please note also that in relation to impacts on biodiversity no direct effects on non-target organisms are expected for the majority of representative uses and no specific concerns for indirect effects on biodiversity were identified. Rather, EFSA concluded that indirect effects may occur, as for any broad-spectrum herbicide or for any other methods that remove weeds – whilst no agreed methodology to assess such effects is available. The Commission will mandate EFSA to develop such a methodology and has included a requirement for the applicant to provide confirmatory data when this methodology is available in the draft Implementing Regulation.

I would like to underline that the draft Implementing Regulation on glyphosate put forward by the Commission is based on the latest scientific knowledge as assessed by the Member States, ECHA and EFSA. The outstanding issues identified by EFSA have been thoroughly considered and conditions and restrictions included to address them.

Let me conclude by recalling that, if new evidence emergences which, after assessment by ECHA and EFSA leads to the conclusion that the approval criteria are no longer fulfilled, the Commission will act immediately to withdraw the approval.

Yours sincerely,

Klaus Berend

c.c. Ms M. Tiramani (EFSA)
Mr P. Ryan (ECHA)