Brussels 26/07/2023

Subject: Oppose to the fast-track renewal of glyphosate and prioritise the protection of human health and the environment

Dear members of the Standing Committee of Plants Animals Food and Feed,

With this letter, PAN Europe would like to express profound concerns about the current developments in the EU assessment of glyphosate, particularly the deviation from democratic procedures and the apparent downplaying of the adverse effects of glyphosate and its products favouring the renewal of its approval. Above all we urge you to promptly take action to address the issues outlined in this letter and ensure strict compliance with transparency rules and democratic EU law provisions aimed at safeguarding human, animal, and environmental health from harmful pesticides. Given the popularity of glyphosate-based products in Europe, there is a widespread exposure of the general population, including children[1]. Consequently, accurately identifying their toxicity and protecting them from exposure is urgent.

1. Procedural issues to fast track the renewal of glyphosate's approval

On the 6th of July, while the Commission and Member States received EFSA's comprehensive peer review of glyphosate's risk assessment, the public had access to nothing more than a mere 2-page summary. In the meantime, as a leaked document revealed, the Commission moved forward at full speed to renew the licence of glyphosate and drafted a renewal report in less than 3 working days, which was presented to you at the subsequent week's SCoPAFF meeting on 11-12th of July. Such discussions typically should occur only when the entire EFSA peer review is available to the public, not just a 2-page summary (Reg 844/2012; Art 13 & 14). Nevertheless, this clearly provides insufficient time even for you to carry out a thorough examination of the peer review of glyphosate. Moreover, not only did the Commission rush to present a renewal report on glyphosate but also occulted this discussion point from the agenda and did not make it public to the register of the July SCoPAFF meeting documents, clearly going beyond of its implementing powers laid down in Article 10 of Reg. 182/2011 on Comitology.

Continuing in full speed, the Commission announced at the ENVI Committee 'exchange of views' meeting of 13 July that it plans to present a renewal Regulation proposal at the ad-hoc SCoPAFF meeting on the 15th of September and invite the Member States to vote at the 11-12th October SCoPAFF meeting. In the meantime, the public and scientific community is not given any opportunity to review EFSA's assessment on glyphosate ahead of the vote. EFSA's complete peer-review conclusions were only made public today (26th July), whereas the background documents including the Renewal Assessment Report and additional data that EFSA received to address the data gaps highlighted in the public consultation, will be made public between August and October. Therefore, it will not be before October that the public and scientific community will be able to scrutinise thousands of pages of documents on the EU assessment of glyphosate, while behind closed doors EU member states will be already voting for its renewal.

[1] HBM4EU Policy Brief Pesticides https://www.hbm4eu.eu/wp-content/uploads/2022/07/HBM4EU_Policy-Brief-Pesticides.pdf

At the same parliamentary meeting, the Commission justified the hasty rhythm on the grounds of wanting to avoid another extension of the glyphosate's approval period. Ironically, during the same SCoPAFF meeting the Commission presented to you a proposal to extend the approval period of no less than 25 pesticide substances. Among them we find flufenacet and chlorotoluron, both candidates for substitution and with known hazardous properties, the approval period of which is to be prolonged for the eighth and seventh time, respectively (!).

In line with the rules laid down in Reg (EC) 844/2012 on renewal procedures aiming for an independent, objective, and transparent assessment of active substances, where the Commission has six months to present a renewal report and draft regulation, we ask you to refuse to adjust to the Commission's high-speed 'modus operandi' and to any proposal for a renewal for the assessment of glyphosate. This is for the procedural issues mentioned above together with the toxicity issues highlighted hereafter.

2. Unlike ECHA's and EFSA's conclusions, and contrary to what the Commission pretends, glyphosate does not fulfil the criteria to be approved under Regulation (EC) 1107/2009.

The provisions of the Regulation (EC) 1107/2009 are underpinned by the precautionary principle to ensure that active substances or products placed on the market should not adversely affect human or animal health or the environment (Reg 1107/2009 Art 1(4)). There is an overwhelming amount of scientific evidence indicating that glyphosate (and glyphosate-based products) can be harmful to humans and non-target species, demonstrating that the approval criteria laid down in Article 4 of 1107/2009 are not met. Nevertheless, the Commission is moving forward with the renewal of its approval, which is highly alarming, especially given the substance's widespread use. Indeed, EFSA has acknowledged outstanding issues in relation to missing data for co-formulants and regarding the impact of glyphosate use on biodiversity, neurotoxicity, and microbiome health. As we explained in a letter to the Director of EFSA, Mr Url [2], these issues should be considered as Critical Areas of Concern (CAoC), according to EFSA's own definition of what a Critical Area of Concern is. In other words, the EFSA conclusions indicate that the approval criteria, which relate to active substances, products and all their ingredients, are not fulfilled. While the public remains in the dark in relation to all the details behind EFSA's conclusion, there are several significant shortcomings in the assessment that, if corrected, will result in the non-renewal of glyphosate's approval, as we will outline below.

Regrettably, EFSA's reliance on ECHA's already questionable classification of glyphosate as 'non-carcinogenic' is deeply concerning. Despite mounting evidence, including IARC's classification of glyphosate as probably carcinogenic to humans[3], as well as the reports from the Superior Health Council in Belgium[4] and the French institute INSERM[5] on the cancer potential of glyphosate, the EU agencies have downplayed its carcinogenicity. Contrary to their claims, the assessment of AGG, ECHA and now EFSA, contradicts the recommendations of the international and EU agreed protocols for

[2] Letter 13th July 2023 "Concerns: EFSA main findings on glyphosate" [link]
[3] IARC monograph on glyphosate (2015) https://www.iarc.who.int/featured-news/media-centre-iarc-news-glyphosate/
[4] Superior Health Council, 2021. Glyphosate and Glyphosate-based formulations No 9561 https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/20200303_shc-9561_glyphosate_vweb.pdf
[5] Inserm. Glyphosate and glyphosate-based herbicides. Extract from « Pesticides and health effects: New data ». Collection Expertise collective. 2021.

carcinogenicity assessment[6]. Furthermore, in 2023, an update of the Agricultural Health Study[7], a study considered by ECHA and EFSA of the highest quality, found an association between glyphosate exposure and oxidative stress in humans that "*may inform evaluations of the carcinogenic potential of this herbicide*". The misclassification of glyphosate stems from a flawed assessment process as seen in the previous reapproval[8], where crucial evidence of its carcinogenicity, such as studies showing promotion of malignant lymphomas and other tumours in animals, and its potential to cause oxidative stress and DNA lesions, has not been acknowledged neither by the Assessment Group on Glyphosate nor by the Risk Assessment Committee (RAC). Furthermore, along with this evidence, the absence of 2 genotoxicity OECD tests in the applicant's dossier raises serious doubts on the completeness of the assessment. While the RAC acknowledged the data gap, the missing studies were never requested nor the other evidence on carcinogenicity was endorsed, leading to the adoption of an equivocal opinion. This reckless disregard for public health and safety is deeply concerning.

Similar concerns are raised regarding the neurotoxicity assessment. A recent review (2022) confirms that glyphosate and glyphosate-based products are neurotoxic to a wide range of animal species and humans[9]. The links between glyphosate exposure and autism in children[10] or Parkinson's disease in adults[11] are alarming. Despite this evidence, there is no developmental neurotoxicity (DNT) study in the glyphosate application dossier for renewal. In fact, the one available on another glyphosate salt (which was originally undisclosed by the companies) indicates developmental neurotoxicity[12] and EFSA's factsheet acknowledges the neurotoxicity potential of GBH. Nevertheless, instead of concluding as a critical area of concern that a risk of developmental neurotoxicity exists and highlight the missing DNT study as a data gaps, EFSA raised no such concerns, whereas AGG and now the Commission proceeded with the renewal of glyphosate's reapproval.

Finally, a plethora of scientific publications report the impact of glyphosate and glyphosate-based products on non-target species and biodiversity. From bee colonies, fish, amphibians, birds, plants and algae, exposure to glyphosate and GBH has been linked to adverse effects that may affect population and therefore biodiversity[13,14]. Considering the vulnerable stage of our ecosystems, it is simply unacceptable that EFSA acknowledges the risk of the use of the studied formulation on biodiversity but does not identify it as a critical area of concern simply because of 'a missing harmonised methodology'. Reapproving their use is a blatant violation of the EU pesticides law that aims to protect environmental species and biodiversity. A similar approach is followed for the impact of the use of

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[6] HEAL report, 2022. How the EU risks greenlighting a pesticide linked to Cancer. Zooming in on the glyphosate renewal dossier. [link]

[7] Chang et al 2023. Glyphosate exposure and urinary oxidative stress biomarkers in the Agricultural Health Study. J Natl Cancer Inst. **11**;115(4):394-404. doi: 10.1093/jnci/djac242

[8] Robinson et al, 2020. Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions. European Journal of Risk Regulation, 11(3), 450-480. https://doi.org/10.1017/err.2020.18

[9] Costas-Ferreira et al (2022) Toxic Effects of Glyphosate on the Nervous System: A Systematic Review. *Int. J. Mol. Sci.* 23, 4605. https://doi.org/10.3390/ijms23094605

[10] Von Ehrenstein et al (2019). Prenatal and infant exposure to ambient pesticides and autism spectrum disorder in children: population based case-control study. *BMJ*. 20;364:l962 https://doi.org/10.1136/bmj.l962

[11] Caballero et al. (2018) Estimated Residential Exposure to Agricultural Chemicals and Premature Mortality by Parkinson's Disease in Washington State. *Int. J. Environ. Res. Public Health* 15, 2885. https://doi.org/10.3390/ijerph15122885

[12] Mie and Ruden, 2022. What you don't know can still hurt you - underreporting in EU pesticide regulation. *Environ Health* 21, 79 (2022). https://doi.org/10.1186/s12940-022-00891-7

[13] PAN Europe, 2023. Glyphosate's impact on bee health [link]

[14] Klatyik et al. (2023) Terrestrial ecotoxicity of glyphosate, its formulations, and co-formulants: evidence from 2010–2023. Environmental Sciences Europe 35, 51 (2023) https://doi.org/10.1186/s12302-023-00758-9

glyphosate on human microbiome and of other species. EFSA has shown how much they disregard the precautionary principle in their work, as defined in the law and the case law.

The EU's glyphosate assessment process has once again a focus on the active substance and a bias towards industry dossiers over peer-review academic literature. As highlighted in EU case law, risk managers should ensure the applicant provides sufficient data to exclude any carcinogenicity or long-term toxicity risk of the product[15]. This is not the case with glyphosate, where the assessment has incorrectly concluded no harm, overlooked toxicity data gaps, and ignored the health and environmental impacts of the representative formulation and its ingredients, all of which justifies a non-renewal. Yet, the Commission is now shifting this responsibility onto you.

Based on the arguments outlined above PAN Europe urgently calls upon you to reject this attempt of fast-track renewal of glyphosate due to all these profound concerns about the EU assessment procedure. Above all, we call upon you to prioritise public health and environmental protection over commercial interests and take a firm stance against glyphosate's renewal to safeguard the wellbeing of citizens and ecosystems, aligning with the precautionary principle and ensuring a safer future for future generations.

Thank you in advance for your consideration,

Sincerely,

Angeliki Lyssimachou

Head of Science and Policy

PAN Europe

[15] See C-616/17: "need to take into consideration the effects of the constituents of a plant protection product as a whole is, moreover, confirmed by the rules laid down in Articles 25 and 27 of Regulation (...) it is clear that the placing on the market of safeners, synergists and co-formulants contained in such a product must also be subject to assessments to determine whether they have any harmful effect" "It is therefore the task of the competent authorities, when examining an application for the authorisation of a plant protection product, to verify that the material submitted by the applicant, and primarily the tests, analyses and studies of the product, is sufficient to exclude, in the light of current scientific and technical knowledge, the risk that that product exhibits such carcinogenicity or toxicity."