

Brussels, 27 June 2024

To: Health, Agriculture and Environment Ministers of EU Member States

Subject: Urgent call to Member States - Oppose the unlawful renewal of glyphosate-based herbicides' national authorisations

Dear Minister,

With this letter, PAN Europe would like to share with you detailed information on how to oppose the renewal of national authorisations for glyphosate-based herbicides (hereafter GBHs) as their use may cause harm to people's health and the environment. The current scientific evidence is unequivocal: GBHs do not meet the safety approval criteria outlined in the European Pesticide Law. At this moment and in the upcoming year, your responsible national authorities will reassess these herbicides and decide on their authorisation. An assessment of GBHs conducted in strict compliance with the European Pesticide Law (Regulation (EC) No 1107/2009) should lead to the non-renewal of national authorisations.

PAN Europe would like to highlight that the EU Pesticide Law is meant to serve as a safeguard for human health and the environment and has established certain approval criteria for both active substances and pesticide products (Article 4). To receive national authorisation, a pesticide product's application must comply with these criteria as explained in the requirements outlined in Article 29. These include demonstrating, among others, that based on current scientific and technical knowledge, the requirements provided for pesticide products in Article 4(3) are met: the use of the GBH causes no harm to human and animal health and no unacceptable effects on the environment (Article 29 (1e)). Regrettably, GBHs fail to meet these fundamental requirements.

The European Food Safety Authority's (EFSA) own glyphosate peer-review conclusions identified important data gaps and outstanding issues associated with GBHs exposure. Specifically, EFSA acknowledged that there are indications that GBHs cause developmental neurotoxicity. EFSA also recognised the evidence indicating adverse effects of glyphosate and GBH exposure on the microbiome. However, for the latter, EFSA refrained from drawing definitive conclusions, citing the lack of internationally agreed guidelines. Regarding biodiversity, EFSA identified high long-term risks to mammals in at least 12 out of the 23 proposed uses of the representative formulation under assessment and could not finalise the risk assessment for aquatic macrophytes exposed via drift. EFSA stated that firm conclusions on biodiversity could not be drawn due to the absence of a harmonised approach for assessing the impact.



The independent scientific literature provides even further evidence of the impacts of exposure to GBHs. Studies link exposure to glyphosate and GBHs to neurotoxicity [1], autism spectrum disorders in children exposed from prenatal age [2], amyotrophic lateral sclerosis [3] and Parkinson's disease in adults [4]. It has also been linked to endocrine disruption [5] and alternations in the microbiome [6]. Last year, the Global Glyphosate Study [7], a multi-institutional international study on glyphosate and two glyphosate-based products, released its first long-term carcinogenicity data following exposure at the "acceptable daily intake" (ADI) level. The results show that low doses of GBHs, assumed to be safe by the EU, caused cases of leukaemia in young rats, following early life exposure. One of the products tested was the representative formulation BioFlow (MON 52276). This study was not taken into account by ECHA and EFSA, as it was not published at the time of their assessments. Clearly all applications for the national authorisation of MON 52276 products should be rejected. The present evidence is a mere overview of why GBHs fail to meet the approval criteria for pesticide products under the EU Pesticide Law. For a more comprehensive analysis, please refer to the dedicated section in our newly published guidance document [8].

Taking into account the widespread use and exposure to glyphosate-based products, neglecting any reported adverse effects poses an unacceptable health risk to farm workers, residents of agricultural zones and the general population since GBHs are used in public and private spaces. It also poses unacceptable risks to the environment, impacting biodiversity and ecosystems. In light of the evidence presented, your national authorities should reject the (re-)authorisation of GBHs in your territories, by concluding that their applications do not meet the requirements of Article 29. Under Articles 36(1)(3) and 43(1) of Regulation (EC) No 1107/2009, such a conclusion provides grounds to refuse both the first national authorisation of a pesticide product or its renewal. In applying these provisions, your national authorities should also invoke the core of the EU Pesticide Law: the precautionary principle (Article 1(4)). In cases where there is uncertainty regarding risks or indications of harm, such as with GBHs, the principle mandates that national authorities must intervene to ensure the high level of protection required by the EU law¹.

Given the above, any decision to renew the national authorisation of GBHs would indicate a failure to comply effectively with the requirements of the European Pesticide Law. We kindly request updates on the assessment of GBHs within your Member State, particularly regarding

¹ The precautionary principle has been further defined by the case-law from the Court of Justice of the EU. The Court considers that the precautionary principle entails competent authorities to not wait until a harm materialises but to act when a risk exists, even when there is a lack of information that does not allow to draw firm conclusions in a risk assessment. Cf. e.g. C-477/14, Pillbox 38, 4 May 2016, EU:C:2016:324, pt. 55; T- 817/14 Zoofachhandel Züpke and Others v. Commission, 17 March 2016, EU:T:2016:157, pt. 51; T-333/10, ATC and Others v. Commission, 16 September 2013, EU:T:2013:451, pt. 81; T-257/07, France v. Commission, 9 September 2011, EU:T:2011:444, pt. 68; T-74/00 e.a., Artedogan e.a. c. Commission, 26 November 2002, EU:T:2002:283, pt. 184. T.



considerations for banning glyphosate or imposing restrictions on its use. Your transparency in this matter would be greatly appreciated.

As Ministers of the Environment, Health, or the Agriculture, entrusted with safeguarding the health of your citizens and the environment, we urge you to ensure that your respective authorities do not grant or renew the national authorisations of glyphosate-based herbicides. The protection of farmers, agricultural workers, and the public, as well as our biodiversity, hangs in the balance.

Thank you in advance for your consideration,

Yours sincerely,

Angeliki Lysimachou, PhD Head of Science and Policy PAN Europe



Notes:

- [1] Costas-Ferreira et al, 2022. Toxic Effects of Glyphosate on the Nervous System: A Systematic Review. *Int. J. Mol. Sci.* 2022, 23, 4605. https://doi.org/10.3390/ijms23094605
- [2] von Ehrenstein et al, 2019. Prenatal and infant exposure to ambient pesticides and autism spectrum disorder in children: Population based case-control study. BMJ, I962. https://doi.org/10.1136/bmj.I962
- [3] Andrew et al, 2021. Pesticides applied to crops and amyotrophic lateral sclerosis risk in the U.S. *NeuroToxicology*, 87, 128–135. https://doi.org/10.1016/j.neuro.2021.09.004
- [4] 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
- [5] Lesseur C et al, 2021. Maternal urinary levels of glyphosate during pregnancy and anogenital distance in newborns in a US multicenter pregnancy cohort *Environ Pollut*. 10.1016/j.envpol.2021.117002
- [6] Mesnage R et al, 2021. Use of Shotgun Metagenomics and Metabolomics to Evaluate the Impact of Glyphosate or Roundup MON 52276 on the Gut Microbiota and Serum Metabolome of Sprague-Dawley Rats" *Environ Health Perspect*. https://doi.org/10.1289/EHP6990
- [7] Panzacchi, S., Tibaldi, E., De Angelis, L., Falcioni, L., Gnudi, F., Iuliani, M., Manservigi, M., Manservisi, F., Manzoli, I., Menghetti, I., Montella, R., Noferini, R., Sgargi, D., Strollo, V., Antoniou, M., Chen, J., Dinelli, G., Lorenzetti, S., Mesnage, R., ... Mandrioli, D. (2023). Leukemia in Sprague-Dawley Rats Exposed Long-Term from Prenatal Life to Glyphosate and Glyphosate-Based Herbicides. https://doi.org/10.1101/2023.11.14.566013.
- [8] PAN Europe (2024), *Guidance document: BANNING GLYPHOSATE-BASED HERBICIDES AT NATIONAL LEVEL.* URL: https://www.pan-europe.info/resources/reports/2024/06/banning-glyphosate-based-herbicide-national-level.