Pesticide Action Network Europe

To: Ms Sandra Gallina
Director-General
Directorate-General for Health and Food Safety (SANTE)
European Commission

Brussels, 23 January 2025

Subject: Call to propose the non-renewal of fenoxaprop-P-ethyl and fludioxonil

Dear Ms. Gallina,

With this letter, PAN Europe would like to urge the European Commission to swiftly propose the non-renewal of two pesticide active substances following their identification as endocrine disruptors by the European Food Safety Authority (EFSA). The two substances, fenoxaprop-P-ethyl and fludioxonil, pose a public health risk and do not comply with the requirements of Regulation 1107/2009, which aim to ensure a high level of protection of human health and the environment. We call upon the Commission to present such non-renewal proposals to the Member States during the upcoming Standing Committee on Plants, Animals, Food, and Feed (SCoPAFF) meeting on 11 and 12 March.

According to Article 4 of Regulation 1107/2209, an active substance shall only be approved if it may be expected - taking into account the approval criteria set out in points 2 and 3 of Annex II- that products containing the active substance and their residues have no harmful effects on human health, including that of vulnerable groups, and no unacceptable effect on the environment. Points 3.6.5 and 3.8.2 of Annex II specify that a substance shall only be approved if it is not considered to have endocrine-disrupting properties that may cause adverse effects in humans or non-target organisms. EFSA's conclusions on the peer review of fenoxaprop-P-ethyl and fludioxonil clearly indicate that these two substances clearly do not comply with these requirements.

EFSA's conclusions[1] on the peer review of **fludioxonil**, a candidate for substitution, show the substance meets the endocrine disruption criteria for the EAS-modalities both for humans and non-target organisms (points 3.6.5 and 3.8.2. of Annex II). Namely, fludioxonil was found to decrease testosterone synthesis and increase estradiol leading to delayed sexual maturation,

[1] EFSA, Peer review of the pesticide risk assessment of the active substance fludioxonil, 4 November 2024, EFSA Journal. 2024;22:e9047, https://doi.org/10.2903/j.efsa.2024.9047.

decreased anogenital distance in males and increased oestruscycle in females. Evidence suggests an anti-androgenic mode of action but other modes of action, affecting steroidogenesis and/or oestrogenic pathways, are also plausible. These conclusions for humans also apply to wild mammals as non-target organisms. Moreover, EFSA indicated that several other important issues of fludioxonil risk assessment could not be finalised. Firstly, the batches used in toxicity studies could not be concluded to be representative of both the originally and newly proposed reference specification for the active substance fludioxonil and its associated impurities. Secondly, EFSA was unable to finalise the consumer risk assessment (dietary and drinking water) based on provided data. Lastly, the groundwater exposure assessment could not be finalised for the possible unidentified metabolites MF2 and D9. The company's failure to provide the required data in line with Regulation 283/2013 has led to delays in the risk assessment causing official prolongations of its market approval. As a result, fludioxonil has remained on the market for 17 years, 10 years longer than the legal period allocated to such active substances considered candidates for substitution. Given that fludioxonil is now identified as an endocrine disruptor, its immediate ban is urgent.

According to EFSA's conclusions[2], **fenoxaprop-P-ethyl** is an endocrine disruptor for humans through the A-modality. Specifically, it was shown to induce changes in the weights of the prostate, epididymis, and testes, alongside alterations in testicular weight. We are particularly concerned by EFSA's conclusions that highlight significant data gaps in ED assessment, including the absence of a level 5 study, even though this was required by the applicant under the ECHA/EFSA Guidance Document and explicitly requested by the peer review experts in 2019. This data gap is unacceptable, especially given that the applicant was granted a three-year (2019–2022) assessment 'stop clock' to address it. This resulted in multiple extensions of the approval period for fenoxaprop-P-ethyl up to 2025, which was initially set to expire in 2018. Despite this data gap, the current scientific evidence is sufficient. PAN Europe fully supports EFSA's peer review experts, who emphasised the need to accept a higher level of uncertainty and conclude that fenoxaprop-P-ethyl meets the criteria for endocrine disruption. For non-target organisms, the data gaps were found to be too significant to determine the endocrine-disputing potential of fenoxaprop-P-ethyl *via* the EAS modalities. Further data gaps from the applicant resulted in unfinalised issues in the assessment of EFSA's peer review making it impossible to conclude i) whether the proposed levels of all impurities are toxicologically acceptable; ii-iii) the consumer risk assessment and iv) the risks for aquatic organisms. There is no justification for requesting additional data to address these data gaps, as the substance is an endocrine disruptor for human health, and therefore does no longer meet the criteria to be approved.

Moreover, based on the above, the Commission should take measures to ensure that applicants comply with data requirements. If such data is not provided within the given timelines, the application should be considered inadmissible, resulting in the withdrawal of the substance's approval. These delays come at the expense of both public health and the environment.

[2] EFSA, Peer review of the pesticide risk assessment of the active substance fenoxaprop-P-ethyl, 13 November 2024, EFSA Journal. 2024;22:e9053, https://doi.org/10.2903/j.efsa.2024.9053.

In conclusion, the approvals of these two dangerous substances were initially set to expire in 2018, but have been extended to 2025 due to several delays in risk assessment. As a result, farmers, residents of agricultural areas, bystanders, and European consumers are exposed to unnecessary health risks that EU law is intended to prevent. Without further delay and in line with Article 13(5) of Regulation 844/2012, we urge the European Commission to propose the non-renewal of fenoxaprop-P-ethyl and fludioxonil ahead of the next Standing Committee on phytopharmaceuticals. Considering the reasons for not renewing the approval relate to concerns for human health and the environment, and in line with Article 20 of Regulation 1107/2009, no grace period for the sale, distribution, disposal, storage and use of existing stocks should be granted and the pesticide products concerned should be withdrawn immediately.

We trust that the European Commission will take decisive action to protect public health and the environment by ensuring the immediate ban of these hazardous substances, without further delay.

Sincerely yours,

On behalf of PAN Europe

Dr. Angeliki Lysimachou
Head of Science and Policy
Pesticide Action Network Europe