Pesticide Action Network Europe

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

Brussels, 23 June 2025

Subject: Call for a swift ban on four known endocrine-disrupting pesticides

Dear Ms. Gallina,

With this letter, PAN Europe urges the European Commission to promptly propose the non-renewal of **four pesticide active substances identified as endocrine disruptors by the European Food Safety Authority (EFSA)**[1]. The Pesticide Regulation (1107/2009), which aims to ensure a high level of protection for human health and the environment, prohibits the approval of substances with such harmful properties. We call upon the Commission to **present these non-renewal proposals to the Member States during the upcoming Standing Committee on Plants, Animals, Food, and Feed (SCoPAFF) meeting on 9 and 10 July**. However, we regret that the agenda for the July meeting does not include proposals for banning these harmful substances.

According to Article 4 of the Pesticide Regulation, 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 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, unless the exposure is negligible. EFSA's conclusions on the peer review of fludioxonil, bruprofezin, fenoxaprop-P-ethyl, and cyprodinil clearly indicate that these substances do not comply with these requirements. Below we provide some specific details.

[1] Bruprofezin, cyprodinil, fenoxaprop-P-ethyl and fludioxonil.

Buprofezin[2] meets the endocrine disruption criteria for the T-modality. The substance was found to disrupt the Hypothalamic-Pituitary-Thyroid (HPT) axis, generating changes in thyroid weight and thyroid histopathology. These adverse effects were deemed applicable to humans and wild mammals.

Cyprodinil[3] meets the endocrine disruption criteria for the EAS-modalities for humans and wild mammals and other non-target organisms. The substance leads to clear endocrine-mediated effects on both female and male reproductive health. For humans, cyprodinil was found to induce delayed sexual maturation and decrease ano-genital distance (AGD). This conclusion is considered relevant for wild mammals based on the observed adverse effects on reproductive performance. In fish, cyprodinil increased male vitellogenin levels, resulted in changes in female gonad histology and decreased fecundity and fertilisation success.
Furthermore, EFSA concluded there was no safe use of cyprodinil for mammals and aquatic organisms.

Fenoxaprop-P-ethyl[4] 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, along with alterations in testicular weight.

Fludioxonil[5] meets the endocrine disruption criteria for the EAS-modalities for human health and non-target organisms according to EFSA. Namely, fludioxonil was found to decrease testosterone synthesis and increase estradiol, leading to delayed sexual maturation, decreased anogenital distance in males and increased oestrus cycle in females. These conclusions for humans also apply to wild mammals as non-target organisms.

Furthermore, fludioxonil meets the OECD definition of PFAS and was found to be very persistent, raising further concerns about its long-term impact on human health and the environment. Worringly, fludioxonil was the most frequently detected candidate for substitution in European fruit between 2009 and 2019, according to data from the EU Multiannual Control

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[2] EFSA, Peer review of the pesticide risk assessment of the active substance buprofezin, 1 April 2025, https://doi.org/10.2903/j.efsa.2025.9392
[3] EFSA, Peer review of the pesticide risk assessment of the active substance cyprodinil, 6 February 2025, https://doi.org/10.2903/j.efsa.2025.9209
[4] EFSA, Peer review of the pesticide risk assessment of the active substance fenoxaprop-P-ethyl, 13 November 2024, https://doi.org/10.2903/j.efsa.2024.9053.
[5] EFSA, Peer review of the pesticide risk assessment of the active substance fludioxonil, 4 November 2024, https://doi.org/10.2903/j.efsa.2024.9047.

Programme analysed by PAN Europe[6], confirming European consumers' exposure to this chemical.

We wish to emphasise that the derogation set out in Article 4(7) of the Pesticide Regulation cannot apply to these four substances. Article 4(7) foresees that, on the basis of documented evidence included in the application, a substance that does not meet the requirements of points 3.6.5 and 3.8.2 of Annex II may exceptionally be approved for a period not exceeding five years to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods. However, Article 13(5) of Regulation 844/2012, which sets out the renewal procedure[7] makes clear that all relevant information shall be provided by the applicants by the end of the submission period and will otherwise not be taken into account. The applicants for the renewal of these four substances did not provide the necessary information to apply for a renewal under the conditions of Article 4(7) in their application. As a result, it is not legally possible to proceed with the renewal of any of these four harmful substances.

In January 2023[8], we already called upon the Commission to propose the non-renewal of two of the substances, fenoxaprop-P-ethyl and fludioxonil, for which EFSA's conclusions were published last year (November 2024). We regret that such proposals were not presented to the Member States during the SCoPAFF meetings of March or May, and still do not appear on the agenda of the next meeting planned in July. The harmful properties of these substances have been established by EFSA and therefore it is clear that they do not meet the legal requirements of the Pesticide Regulation. It is the Commission's responsibility to ensure they are removed from the EU market without further delays.

Furthermore, there have already been considerable delays in completing the risk assessment of these endocrine-disrupting substances. Their approvals were initially set to expire in 2017 (cyprodinil), 2018 (fludioxonil and fenoxaprop-P-ethyl), or 2021 (buprofezin) but have been extended multiple times. Therefore, the current delays in decision-making are unacceptable, as they add further setbacks to an already prolonged process. They result in farmers, residents of agricultural zones and European consumers being exposed to these harmful chemicals, well beyond the expiry of their original approval period.

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[6] PAN Europe, Forbidden Fruit, May 2022.

[7] While being repealed, Regulation (EU) No 844/2012 continues to apply to the active substances for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

[8] 20250121_Call to propose the non-renewal of fenoxaprop-P-ethyl and fludioxonil

Pesticide Action Network Europe

We trust that the European Commission will take decisive action to protect public health and the environment by presenting the proposals to Member States to ban these four hazardous substances, without further delay.

Sincerely yours,

On behalf of PAN Europe

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