

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

Brussels, 7/11/2024

Subject: Urgent call to propose the non-renewal of flufenacet - A PFAS endocrine disruptor, toxic for the aquatic environment, and emitting TFA.

Dear Ms. Gallina,

We, the 49 undersigned organisations committed to protecting human health and the environment, **call on the European Commission to ensure that the active substance flufenacet is swiftly banned in the EU**. According to the conclusions of the European Food Safety Authority (EFSA), flufenacet is an endocrine disruptor, with the potential to impact the developing brain in children and therefore does not meet the approval criteria set out in the Pesticide Regulation 1107/2009. It is also a per- and polyfluoroalkyl substance (PFAS) and an important source of emission of Trifluoroacetic Acid (TFA), an ultra-short PFAS that is now detected even in our most pristine water resources. The upcoming **Standing Committee on Plants, Animals, Food, and Feed (SCoPAFF) meeting on 4 and 5 December** presents a critical opportunity to act in the best interest of EU citizens, especially vulnerable groups such as young children, and of the environment. We call upon the Commission to present a proposal for the non-renewal of flufenacet to the Member States and work towards its prompt adoption.

Flufenacet was approved for 10 years in January 2004, primarily for use as a herbicide on winter crops such as wheat, rye, spelt and barley. Delays in its risk assessment led to a prolongation of over 11,5 additional years of its approval period, which is now set to expire in June 2025. On 27 September 2024, EFSA's conclusions from its peer review were finally published¹, indicating that the substance does not comply with the approval criteria. As a result, immediate action is needed to ban it before June 2025. These EFSA's conclusions also support our long-standing claim that the continued prolongation of pesticide substances, without taking into account the latest scientific evidence and the precautionary principle, fails to uphold the high level of protection for human health and the environment required by the Pesticide Regulation².

In its conclusions, EFSA highlights two critical areas of concern requiring a ban on flufenacet in accordance with the Pesticide Regulation. Firstly, flufenacet was considered to meet the endocrine disruption criteria for humans and non-target organisms. This conclusion was

¹ European Food Safety Authority, Peer review of the pesticide risk assessment of the active substance flufenacet, September 2024, [DOI: 10.2903/j.efsa.2024.8997](https://doi.org/10.2903/j.efsa.2024.8997).

² PAN Europe, PAN Europe takes legal action against systematic prolongation of permits for toxic pesticides' by the European Commission, [July 2022](#).

reached based on the available and sufficiently investigated dataset. Flufenacet was found to alter the thyroid-stimulating hormone leading to changes in thyroid weight and thyroid histopathology. A clear mode of action was identified in line with Regulation 2018/605. Moreover, alterations of the thyroid hormone could induce developmental neurotoxicity as observed in a developmental neurotoxicity study about flufenacet according to EFSA. These conclusions also apply to wild mammals as non-target organisms. In accordance with Article 4(1) as well as points 3.6.5 and 3.8.2 of Annex II of the Pesticide Regulation, a substance having endocrine-disrupting properties for humans and/or non-target organisms shall not be approved.

Secondly, flufenacet was found to be highly toxic to algae in virtually all the relevant scenarios. Consequently, EFSA identified this as another critical area of concern, preventing its renewal.

Finally, EFSA's conclusions raised additional concerns, including the failure to complete the consumer risk assessment and to address the toxicological relevance of certain metabolites, such as trifluoroacetic Acid (TFA), a common metabolite of several PFAS pesticides. Although this last point has not been identified by EFSA as a third 'red flag' stopping the renewal of flufenacet, TFA is another critical reason supporting the substance's ban. Flufenacet meets the OECD definition of PFAS as it contains a C-CF₃-group. In addition to being persistent, it has been known since 2014³ that it breaks down into the concerning metabolite TFA. TFA is an ultra-short PFAS, which highly contaminates our water resources all across Europe, including our groundwater and drinking water. It is even detected in mineral waters and most pristine water resources⁴. This is of significant concern as knowledge about the substance's toxicity is increasing. TFA has been proposed for hazard classification as toxic for reproduction category 1B, acute toxic 3, very persistent and very mobile (vPvM) and persistent, mobile and toxic (PMT). These classification proposals, make TFA a toxicologically 'relevant metabolite'⁵. In line with the Pesticide Regulation, an active substance shall not be approved if its relevant metabolite(s) are likely to contaminate groundwater above the legal limit of 0.1 µg/L set out in the Water Framework Directive⁶. In its conclusions, EFSA found that the use of flufenacet would result in TFA levels exceeding not only the limit for relevant metabolites (0.1 µg/L) but even the one for non-relevant metabolites (10 µg/L).⁷ Therefore, the Commission's proposal for the non-renewal of flufenacet should identify TFA as the relevant metabolite and mention

³ European Food Safety Authority, Reasoned opinion on the setting of MRLs for saflufenacil in various crops, considering the risk related to the metabolite trifluoroacetic acid (TFA), February 2014, <https://doi.org/10.2903/j.efsa.2014.3585>

⁴ PAN Europe, TFA in Water: Dirty PFAS Legacy Under the Radar, [May 2024](#).

PAN Europe, TFA: The Forever Chemical in the Water We Drink, [July 2024](#).

⁵ Directorate-General for Health and Food Safety, Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under Regulation (EC) No 1107/2009, [Sanco/221/2000 – rev.11](#).

⁶ Points 2.5.1.2 of Part I and 2.7.3 of Part II of the Uniform Principles (Regulation (EU) No 546/20112).

⁷ Under the Pesticide Regulation, a substance must not be approved if its relevant metabolites contaminate groundwater above the 0.1 µg/L limit set by the Water Framework Directive. EFSA's conclusions show TFA levels of over 0.75 µg/L for all flufenacet uses, and in some cases, more than 10 µg/L.

contamination of groundwater with TFA above the legal limit as the third critical point for which flufenacet shall no longer be approved in the EU.

In 2015, flufenacet had been identified as a candidate for substitution because it met the criteria for being classified as persistent and bioaccumulative (two PBT criteria⁸). In accordance with Article 50 of the Pesticide Regulation, this should have led to its substitution for safer alternatives for human health and the environment, thus reducing the level of exposure to this substance. In fact, recent analyses have shown that sales of flufenacet have risen steadily over the last decade in several Member States, reflecting an increase in the use of this substance⁹. Based on sales figures, the Federal Environment Agency of Germany identified flufenacet as the most important pesticide source of TFA¹⁰.

In line with Article 20 of Pesticide Regulation, the Commission should now present a proposal for the non-renewal of flufenacet to the Member States during the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals on 4 and 5 December. If this proposal is supported by a qualified majority of Member States, a vote should be taken at the same meeting to ensure a ban of the substance and immediate withdrawal of authorisations of flufenacet products from the market.

Given the evidence of the toxicity of the substance, the urgency to ban all TFA-emitting substances and the fact that its current approval has been prolonged for more than 11 years, no grace period for the sale, distribution, disposal, storage and use of existing stocks should be granted. **The objective to ensure the high level of protection of human health, groundwater and the environment of the Pesticide Regulation takes priority over the objective of improving agricultural production¹¹.**

Thank you for your attention to this urgent matter. We trust you will make the right decision to protect public health and the environment.

Sincerely yours,

Angeliki Lysimachou
Head of Science and Policy
Pesticide Action Network (PAN) Europe

On behalf of:

⁸ Second indent of point 4, Annex II of the Pesticide Regulation 1107/2009.

⁹ Austria: 39.492 tons (2020); Belgium: 62.673.8 tons (2021); France: 804 tons (2021); Germany: 834.608 tons (2021).

¹⁰ Umwelt Bundesamt (German Environment Agency), Reducing the input of chemicals into waters: trifluoroacetate (TFA) as a persistent and mobile substance with many sources, November 2021, [ISSN 2363-829X](#).

¹¹ Confirmed by Case C-162/21, paragraph 48.



Pesticide Action Network Europe

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