To: Ministers of Environment, Ministers of Health and Ministers of Agriculture of the Member States of the European Union

Brussels, 07/11/2024

Subject: **Urgent call to ban flufenacet** - A endocrine-disrupting, PFAS-emitting pesticide

Dear Minister.

We, the 49 undersigned organisations committed to protecting human health and the environment, call on you to press for and support a **ban of the pesticide active substance flufenacet**. The European Food Safety Authority (EFSA), recently concluded that flufenacet is an **endocrine disruptor**, affecting thyroid function which can indirectly impact brain development, placing pregnant women and newborns at risk. Consequently, flufenacet is a dangerous substance that fails to meet the approval criteria of Pesticide Regulation 1107/2009 and should be banned.

Flufenacet is also a per- and polyfluoroalkyl substance (**PFAS**), a group of substances known as 'forever chemicals' because of their persistence. It is also a significant source of Trifluoroacetic Acid (TFA), an ultra-short PFAS detected in groundwater, drinking water, and even pristine water sources all across Europe¹. 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 you to request and support the immediate ban of this dangerous substance from being used in the production of our food. In this letter, we provide all the arguments in support of a ban of flufenacet and the EU and national levels.

Although flufenacet was first approved in January 2004 for 10 years, its risk assessment has been delayed resulting in prolongation of its approval for use until June 2025- more than 11 years past its original approval period- despite the growing evidence on its toxicity. Flufenacet is currently authorised in 25 Member States for use primarily in winter cereal crops such as wheat, rye, spelt and barley.

On 27 September 2024, EFSA published its risk assessment peer review conclusions², highlighting that flufenacet meets the criteria for endocrine disruption in humans. The substance alters the thyroid-stimulating hormone levels leading to changes in thyroid weight and thyroid

¹ PAN Europe, TFA in Water: Dirty PFAS Legacy Under the Radar, <u>May 2024</u>. PAN Europe, TFA: The Forever Chemical in the Water We Drink, <u>July 2024</u>.

² European Food Safety Authority, Peer review of the pesticide risk assessment of the active substance flufenacet, September 2024, <u>DOI: 10.2903/j.efsa.2024.8997</u>.

histopathology. These alterations in the thyroid hormone levels could explain the developmental neurotoxicity observed in an earlier animal study. Therefore, flufenacet may affect the developing brain during pregnancy and early life stages, posing an important risk for the vulnerable groups of our population. These alarming conclusions also apply to wild mammals as non-target organisms. Hence, flufenacet should be banned, in line with the Pesticide Regulation, stipulating that a substance having endocrine-disrupting properties for humans and/or non-target organisms shall not be approved (Article 4(1), as well as points 3.6.5 and 3.8.2 of Annex II).

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 TFA, a common metabolite of PFAS pesticides.

Although EFSA has not identified this last point as a 'red flag' stopping the renewal of flufenacet, its breakdown product **TFA** is another critical reason why the substance must be banned. Flufenacet meets the OECD definition of PFAS. In addition to being persistent, it breaks down into TFA, an ultra-short PFAS which contaminates our water resources all across Europe, including our mineral waters and most pristine water resources. This is of significant concern as the evidence about the toxicity of TFA is increasing. It is currently proposed for classification as 'toxic for reproduction' category 1B, very persistent and very mobile (vPvM) and persistent, mobile and toxic (PMT), among others. These hazard classification proposals make TFA a toxicologically 'relevant metabolite'³. Currently, TFA contaminates groundwater far above the legal limit of 0.1 μ g/L for relevant metabolites. In its conclusion EFSA found that the use of flufenacet would result in levels exceeding not only the limit for relevant metabolites, but even the one for non-toxic metabolites (toxicologically non-relevant), which is 100 times higher (10 μ g/L).⁴

Given this evidence, flufenacet cannot be expected to meet the requirements of Pesticide Regulation, which explicitly states that pesticides shall "have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water" and "no unacceptable effects on the environment" (Article 44). Therefore, we urge you to press for and support an EU ban of flufenacet without delay or grace periods during the upcoming EU SCoPAFF meeting on 4 and 5 December. Moreover, we ask that all national authorisations of products containing flufenacet be withdrawn without waiting for the outcome of these European discussions. The Pesticide Regulation gives Member States a legal basis to review and withdraw authorisation at any time where there are indications that the pesticide use can no longer be considered safe (Article 44) and makes clear that the objective to ensure the high level of protection of human health, groundwater and the environment

³ 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 1107/200, Sanco/221/2000 – rev.11.

 $^{^4}$ Under the Pesticide Regulation, a substance must not be approved if its relevant metabolites contaminate groundwater above the 0.1 $\mu g/L$ limit set by the Water Framework Directive. EFSA's conclusions show TFA levels of over 0.75 $\mu g/L$ for all flufenacet uses, and in some cases, more than 10 $\mu g/L$.

of the Pesticide Regulation takes priority over the objective of improving agricultural production⁵.

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:

Armenian Women for Health and Healthy Environment (Armenia), Elena Manvelyan, President

BeeLife European Beekeeping Coordination, Lars Hellander, President

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⁵ Confirmed by Case C-162/21, paragraph 48.

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