Pesticide Action Network Europe

Mr Bernhard Url
Executive Director
European Food Safety Authority
Parma - Italy

Cc:
Mr Eric Thévenard
Head of Unit E4 'Pesticides and Biocides'
Directorate-General for Health and Food Safety
European Commission
Brussels - Belgium

Brussels, 02/07/2024

Subject: Request to swiftly complete the peer review of flufenacet based on its endocrine-disrupting properties

Dear Mr. Bernhard Url,

PAN Europe is writing to you to urge EFSA to support the identification of flufenacet as an endocrine-disrupting (ED) substance and complete its peer review. This swift action is required to comply with the hazard-based approach of the EU Pesticide Regulation (1107/2009) and ensure a high level of protection for EU citizens, wildlife and our water resources from flufenacet.

Flufenacet was approved in the EU from January 2004 to December 2013. However, because of multiple delays in its renewal procedure, the substance so far has been granted a prolongation of 11 years and 6 months, which has more than doubled its foreseen approval period. Some of these prolongations resulted from the 30-month ED clock-stop granted to the applicant to provide the missing studies from the data requirements to assess endocrine disruption. It is now evident that the applicant's failure to provide a complete application, coupled with the authorities' failure to carry out the assessment in the foreseen time has

resulted in substantial delays, thereby putting at risk the health of EU citizens and the environment in breach of legal requirements. We are particularly critical of the fact that these prolongations persist even now that the ED dataset has been submitted and assessed, leading to the conclusion that flufenacet does not meet the approval criteria set out in points 3.6.5, 3.8.2 of Annex II of the Pesticide Regulation. In this regard, it is clear from the case-law[1] that the criteria set out in points 3.6.5 of Annex II must be interpreted in the same way as the criterion set out in point 3.6.4 of that annex, namely that an active substance 'shall only be approved if' that substance 'is not or has not to be' as having endocrine disrupting effects. It follows that endocrine disrupting properties are an exclusion criterion in the sense of Article 4(1) and thus, the assessment should be finalised. Considering the above provisions and Article 13 of Regulation 844/2012, further delay in assessing flufenacet is a breach of the EU law.

In August/September 2022, based on the reporting table and the revised renewal assessment report submitted to EFSA, experts of the ED working group concluded that flufenacet meets the ED criteria via the T-modality. More specifically, adverse effects on haematological parameters (reticulocyte count and percentage, met-haemoglobin and hematocrit) and organ weight (liver) were induced by flufenacet and a test-item-related perturbation of the hypothalamic-pituitary-thyroid (HPT) axis could not be excluded. In line with the hazard-based approach of the Pesticide Regulation, this requires EFSA to stop further risk assessment and swiftly publish the conclusion of its peer review.

Yet, it came to PAN Europe's attention that the applicant submitted new comparative thyroid assays (CTAs), which were not taken into account by RMS/co-RMS in the context of flufenacet ED assessment. These assays were carried out to determine Triiodothyronine (T3) and Thyroxine (T4) concentration levels in rat serum samples collected during the *in vivo* phase. According to France (co-RMS) and the ED expert group, these CTAs confirmed T3 and T4 disruption, i.e. the former conclusion that flufenacet meets the ED criteria via the thyroid as mode of action. More than six months after the ED expert group delivered its advice (September 2023), it is urgent that EFSA completes its peer review and confirms its preliminary conclusions that flufenacet is an ED for humans and non-target organisms. This is needed for the Commission and Member States to ban flufenacet in the EU ahead of the current expiration date of its approval (June 2025).

Another concern with flufenacet, which supports the critical need for quick action, is that it meets the OECD definition of PFAS. Moreover, its use leads to the formation in plants and soils of the very mobile and very persistent metabolite trifluoroacetic acid (TFA), resulting in groundwater contamination at significant levels. A new report by the Pesticide Action Network and its members highlights alarming levels of TFA in both surface and groundwater samples from ten EU countries[2]. Detected TFA levels ranged from 370 ng/l to 3,300 ng/l, with an average of 1,180 ng/l. Worryingly, this contamination is not confined to industrial hotspots but is widespread. In

[1] Judgement of 4 October 2023, *Ascenza Agro and Industrias Afrasa v Commission*, T-77/20, EU:T:2023:602, paragraphs 118 to 121.

[2] TFA in Water: Dirty PFAS Legacy Under the Radar | PAN Europe (pan-europe.info) - published on 27 May 2024.

rural areas, PFAS pesticides appear to be the primary source of TFA contamination[3]. EU authorities are already aware that flufenacet contributes to the TFA contamination of our water resources. According to the flufenacet renewal report (2017), TFA was demonstrated to leach in groundwater above 0.75µg/L in all of the FOCUS GW scenarios. In a series of these scenarios, it was also found above 10 µg/L, which exceeds the safety threshold even for non-relevant metabolites. In fact, in 2021, the German Environmental Agency (UBA) identified flufenacet as the most significant source of TFA emission in Germany[4]. Considering the above and the current proposal to classify TFA as toxic for reproduction category 1B, it is key to cut the TFA pollution from one of its major sources, i.e. to ban all PFAS pesticides including the endocrine-disrupting flufenacet.

Thank you in advance for your attention to this matter. We look forward to your prompt identification of flufenacet as an endocrine-disrupting pesticide and your conclusion on its non-compliance with the approval criteria of the EU Pesticides Regulation.

Sincerely yours,

On behalf of PAN Europe

Angeliki Lysimachou
Head of Science and Policy
Pesticide Action Network Europe

[3] Trifluoroacetate (TFA): Laying the foundations for effective minimization - Spatial analysis of the entry pathways into the water cycle | Federal Environment Agency (umweltbundesamt.de)
[4] Reducing the input of chemicals into waters: trifluoroacetate (TFA) as a persistent and mobile substance with many sources | Umweltbundesamt