

To: Members of the SCoPAFF Committee - Section "Phytopharmaceuticals - Legislation"

Brussels, 30 June 2025

Subject: EU Standing Committee on Plants, Animals, Food and Feed (SCoPAFF); 9-10 July - position of Pesticide Action Network (PAN) Europe

Dear Members of the SCoPAFF committee,

On July 9th and 10th, you are invited to the EU Standing Committee on Plants, Animals, Food and Feed to discuss and potentially adopt opinions on several European Commission proposals. Ahead of this meeting, we would like to share PAN Europe's position on key issues concerning human health and environmental protection from pesticides. We kindly request that you give these matters your careful attention.

Agenda issues

- Draft Commission Regulation (EU) amending Regulation (EU) 2024/1487 as regards the adoption of the work programme for the gradual review of safeners and synergists (B. 02)
- 2. Draft Commission Implementing Regulation (EU) amending the approval period of the PFAS active substance penthiopyrad (B. 05)
- 3. Draft Commission Implementing Regulation (EU) extending the approval periods of active substances including endocrine-disrupting buprofezin and TFA-emitting cyflumetofen (B. 06)
- 4. Draft Commission Implementing Regulation non-renewing the approval of the PFAS active substance flutolanil (C. 05)
- 5. EFSA conclusions on the PFAS active substance penoxsulam (A. 04)
- 6. Active substances meeting the criteria for endocrine disruption: bruprofezin, cyprodinil, fludioxonil, and fenoxaprop-P-ethyl (A. 05)
- Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment (A. 07)
- 8. TFA (A.10)

1. Draft Commission Regulation (EU) amending Regulation (EU) 2024/1487 as regards the adoption of the work programme for the gradual review of safeners and synergists (B. 02)

PAN Europe welcomes the European Commission's draft Regulation aimed at amending Regulation (EU) 2024/1487. We note that, compared to the version submitted for public consultation, the draft of Annex I in discussion has seen the removal of substances for which no request for inclusion in the work programme was received. We understand this reflects the Commission's obligation under Article 5 of Regulation (EU) 2024/1487 to adopt a decision to formally exclude these substances from the work programme, but regret that the required decision, due by 19 June 2025, has not yet been adopted.

Once adopted by the Commission, we call on all Member States to identify and withdraw national authorisations for all pesticide products containing excluded safeners and synergists. Such products should no longer remain on the market, as they contain substances that will not be assessed at EU level under the revised procedure or the updated data requirements set out in Regulation (EU) 2024/1487.

Allowing such products to remain available would directly contradict the objectives of the new framework, which aims to ensure that safeners and synergists contained in authorised pesticide products are all subject to a harmonised risk assessment. Continuing their use pending the end of the work programme for a gradual review of safeners and synergists creates an uneven playing field and risks undermining public and environmental protection, as there is no guarantee that these excluded substances meet current safety standards.

PAN Europe invites you to support the draft regulation while urging **the European Commission to swiftly adopt the required decision to exclude certain safeners and synergists** from the EU pesticide review programme, as mandated by Regulation (EU) 2024/1487. Once adopted, Member States should promptly withdraw national authorisations for products containing these excluded substances.

2. Draft Commission Implementing Regulation (EU) amending the approval period of the PFAS active substance penthiopyrad (B. 05)

We take note of the applicant's decision to withdraw its application for the renewal of approval of the PFAS substance penthiopyrad. We welcome the Commission's proposal to shorten its approval period to 31 December 2025.

Given that penthiopyrad is a PFAS containing a $-CF_3$ group, and thus a potential precursor to TFA (trifluoroacetic acid), a highly mobile and highly persistent substance that is underway for classification as toxic for reproduction category 1B, and that strongly contaminates

groundwater, we urge you to support the Commission's proposal and to ensure the swift withdrawal of authorisations for all products containing penthiopyrad.

3. Draft Commission Implementing Regulation (EU) extending the approval periods of active substances including endocrine-disrupting buprofezin and TFA-emitting PFAS cyflumetofen (B. 06)

One more time, PAN Europe deplores the Commission's proposal to extend the approval period of a series of active substances suspected or known to cause harm to human health and the environment.

- Buprofezin meets the endocrine disruption criteria for the thyroid modality (T-modality), as confirmed in EFSA's finalised and published peer review conclusions. In animal studies, the substance was shown to disrupt the Hypothalamic–Pituitary–Thyroid (HPT) axis, causing adverse effects such as changes in thyroid weight and modification of histopathology. These effects were considered relevant to both humans and wild mammals. As such, buprofezin fails to meet the approval criteria set out in points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009. Given that the risk assessment has been completed and clearly demonstrates the non-compliance of the substance with EU pesticide legislation, buprofezin should be banned, instead of granted prolonged approval. As a cut-off substance, prolonging such a substance is unlawful.
- **Cyflumetofen** meets the OECD definition of a PFAS and degrades into TFA, as demonstrated in a rotational crop metabolism study. Given the proposed classification of TFA as toxic for reproduction 1B, making it a relevant metabolite, and the widespread pollution of European groundwater routinely above the limit value of 0.1µg/L, TFA-emitting substances should be withdrawn from the EU market at once.

In light of these concerns, we urge Member States to **reject the Commission's proposal** for extending the approval of these substances, and present instead a proposal for their non-renewal.

4. Draft Commission Implementing Regulation non-renewing the approval of the PFAS active substance flutolanil (C. 05)

We reiterate our call for you to support the non-renewal of the PFAS and TFA-emitting flutolanil without further delay.

Flutolanil meets the OECD definition of PFAS because it contains a trifluoromethyl group (-CF₃) bound to a carbon atom. It has been identified as persistent (P) to very persistent (vP) by EFSA.

Moreover, due to its molecular structure ($-CF_3$ group), and as confirmed by EFSA, flutolanil eventually breaks down into TFA, contaminating crops, soil and water resources. TFA is an ultra-short PFAS, highly persistent, mobile, and soluble in water, which is currently undergoing assessment for its harmonised classification as Persistent, Mobile and Toxic (PMT), very Persistent very Mobile (vPvM) and toxic for reproduction category 1B. The latter proposed classification is based on repeated evidence of clear developmental toxicity, including malformations of the eyes and skeletal system in rabbit offspring.

This results in TFA being a 'relevant' metabolite, according to Article 3, point 32 of Regulation (EC) No 1107/2009, which means the 0.1 µg/L groundwater limit applies to TFA. Alarmingly, TFA contamination in groundwater routinely exceeds this limit for relevant metabolites¹ and in some cases surpasses even the 10 µg/L threshold for non-relevant metabolites in groundwater². According to recent scientific warnings, TFA poses a serious threat to planetary boundaries, as most of the TFA released today will persist in the environment for future generations³. Continued use of TFA-emitting substances will lead to the accumulation of this truly forever chemical in our environment. This constitutes a clear indication of a violation of the Pesticide Regulation (EC) 1107/2009, namely its Article 4(3), stating pesticides shall have no immediate or delayed effects on human health, directly or through drinking water, or on groundwater. TFA-emitting substances, including flutolanil, constitute a clear risk for citizens and groundwater and should be banned.

5. EFSA conclusions on the PFAS active substance penoxsulam (A. 04)

As highlighted by EFSA in its conclusions, penoxsulam meets the OECD definition of a PFAS and exhibits moderate to high persistence in the environment. Its molecular structure contains a trifluoromethyl group ($-CF_3$), making it a potential precursor to TFA. Given the widespread TFA pollution already present in European environments and the growing body of evidence on its potential harm to human health and ecosystems, the approval of any $-CF_3$ -containing substance should be prevented to ensure the protection of human health and water resources.

While the renewal dossier for penoxsulam did not report TFA formation in plant residue, rotational crop, dietary, or soil metabolism studies, this lack of detection cannot be interpreted as evidence that TFA is not formed. Standard degradation studies (e.g. OECD 307) are limited to 120 days, which may be insufficient for detecting late-forming degradation products such as TFA, particularly when the parent compound or other metabolites are persistent. In soil studies, penoxsulam was found to break down into several PFAS metabolites containing a $-CF_3$ group, and which therefore could be converted to TFA. Moreover, significant unknown fractions were

¹ Austria, Denmark

² Germany, Sweden, Switzerland.

³ The Global Threat from the Irreversible Accumulation of TFA | Environmental Science & Technology

found in some of the soil metabolism studies, which may represent TFA. As a result, the current data do not rule out TFA formation by penoxsulam.

Additionally, other shortcomings with the degradation studies is that radioactive labelling may be placed on parts of the molecule that are not linked to TFA formation, as well as that the analytical methods employed are poorly suited to detect TFA due to its high polarity and small molecular size.

Furthermore, penoxsulam itself poses a significant risk of groundwater contamination, with concentrations predicted to exceed the drinking water threshold of 0.1 μ g/L in six out of seven FOCUS scenarios for its representative use on chicory. This directly contradicts EU groundwater protection standards.

In light of its classification as a PFAS, its potential for TFA emissions, and the risk of groundwater contamination, we call on you to support the non-renewal of the active substance penoxsulam.

6. Active substances meeting the criteria for endocrine disruption: bruprofezin, cyprodinil, fludioxonil, and fenoxaprop-P-ethyl (A. 05)

As highlighted in our previous SCoPAFF positions, recent conclusions by EFSA have confirmed that several substances currently under renewal clearly meet the criteria for endocrine disruption, and as such, no longer fulfil the conditions for reapproval under the Pesticide Regulation. The substances concerned, buprofezin⁴, cyprodinil⁵, fenoxaprop-P-ethyl⁶ and fludioxonil⁷, cause harmful effects on human health and the environment.

Article 4 and points 3.6.5 and 3.8.2 of Annex II of the Pesticide Regulation clearly provide that active substances having endocrine-disrupting properties cannot be approved unless exposure is negligible. EFSA's findings make evident that this 'negligible exposure' condition was not demonstrated for these substances. Moreover, as the legal requirements under Article 4(7) for exceptional approval have not been satisfied in time by applicants, renewal under this derogation is not permissible for any of these four substances.

⁴ EFSA, Peer review of the pesticide risk assessment of the active substance buprofezin, April 2025, <u>https://doi.org/10.2903/j.efsa.2025.9392</u>

⁵ EFSA, Peer review of the pesticide risk assessment of the active substance cyprodinil, February 2025, <u>https://doi.org/10.2903/j.efsa.2025.9209</u>

⁶ EFSA, Peer review of the pesticide risk assessment of the active substance fenoxaprop-P-ethyl, November 2024, <u>https://doi.org/10.2903/j.efsa.2024.9053</u>

⁷ EFSA, Peer review of the pesticide risk assessment of the active substance fludioxonil, November 2024, <u>https://doi.org/10.2903/j.efsa.2024.9047</u>

In our letter of 23 June 2025⁸, we expressed our deep concern to the Commission regarding the SCoPAFF committee's continued failure to take decisive action to ban these harmful substances. These repeated delays in decision-making are unacceptable and contribute to further setbacks in what has already been a prolonged evaluation process for all four substances. In particular, the latest delay has led to a proposal by the Commission to extend the approval period for buprofezin, which we strongly urge you to oppose (Agenda item B.06).

We therefore call on you to take a clear and firm stance in favour of the **non-renewal of all four endocrine-disrupting active substances**.

7. Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment (A. 07)

In January 2023, the Court of Justice of the EU clarified⁹ that providing emergency authorisations under Article 53 to pesticides that were banned for health and environmental reasons goes against the Pesticide Regulation 1107/2009. Two years and a half later, it is unacceptable that the guidance document on Article 53 derogations has still not been updated. PAN Europe considers that substances that did not receive approval due to an evaluation from EFSA must also not be given derogations. PAN Europe has identified that several Member States providing derogations such substances keep to (diquat, chloropicrin. 1,3-dichloropropene, neonicotinoids), in contradiction with the ruling. PAN Europe asks to update the guidance document in full respect of the ruling.

8. TFA (A. 10)

We would like to bring to your attention a new report *The Forever Chemical in our Daily Bread*¹⁰, published on June 3rd by our Austrian member organisation, GLOBAL 2000. The findings raise serious concerns about the widespread food contamination with trifluoroacetic acid (TFA) and provide critical evidence of the urgency to ban PFAS pesticides.

The study analysed 48 cereal products purchased in Austria, including bread, pasta, breakfast cereals, cornflakes, and flour, sourced equally from organic and conventional farming. The key findings include:

• <u>TFA was detected in all 48 samples</u>, with concentrations ranging from 13 µg/kg (organic rye) to 420 µg/kg (conventional butter biscuits).

⁸ 20250623_Call for a swift ban on four known endocrine-disrupting pesticides

⁹ Ruling of 23 January 2023 in case C-162/21

¹⁰ <u>The Forever Chemical in our daily bread</u>, June 2025.

- Conventional products were, on average, 3.5 times more contaminated than organic ones. Still, all 24 organic products tested exceeded 10 µg/kg, indicating widespread environmental distribution of TFA.
- Compared with the only official EU study on TFA in cereals from 2016/2017, contamination levels have tripled in less than a decade.

The report also includes a health risk assessment based on recent tolerable daily intake (TDI) values derived by the Dutch and the Flemish authorities. These values consider the limited toxicological data available for TFA and draw on increasing evidence regarding structurally related PFAS, which the older value of EFSA (2014) does not. Based on average cereal consumption data:

- For children, the Dutch (RIVM 2023¹¹) TDI is exceeded by a factor of 4, while for adults by a factor of 1.6.
- Cereal consumption alone already reaches 50% of the Flemish TDI (ZORG, 2024¹²) for children and 20% for adults.

These figures are particularly concerning given that cumulative exposure from other dietary sources (e.g., fruits, vegetables, and drinking water) is not accounted for.

With ongoing discussion about regulating PFAS pesticides and TFA, we believe this study provides further evidence of the urgency of banning **all PFAS pesticides**.

Thank you in advance for your consideration of these matters.

Sincerely yours,

On behalf of PAN Europe Angeliki Lysimachou Head of Science and Policy

Contact details:

Dr Angeliki Lysimachou, Head of Science and Policy, <u>angeliki@pan-europe.info</u>, +32 2 318 62 55 Salomé Roynel, Policy Officer, <u>salome@pan-europe.info</u>, +32 451 02 31 33 PAN Europe, Rue de la Pacification 67, 1000, Brussels, Belgium <u>Who we are | PAN Europe</u>

¹¹ RIVM, <u>Advice 14434A02 – Drinking water guideline value for trifluoroacetic acid</u>.

¹² ZORG: <u>In-depth analysis of the selection process for the health-based guideline value for trifluoroacetic</u> acid (TFA) in drinking water (2024).