Pesticide Action Network Europe

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

Brussels, 25 September 2025

Subject: EU Standing Committee on Plants, Animals, Food and Feed (SCoPAFF); 1-3 October; position of Pesticide Action Network (PAN) Europe

Dear Members of the SCoPAFF committee,

On 1 to 3 October, 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

1. Draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of active substances including the PFAS diflufenican, the reprotoxic and PFAS flurochloridone and the suspected endocrine disruptor difenoconazole (B.02)
2. Draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2023/564 as regards the transfer into electronic format of the records of plant protection products kept by professional users (B. 03)
3. Draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the PFAS flutolanil (C.06)
4. EFSA conclusions on the PFAS active substance penoxsulam, the reprotoxic substance halosulfuron-methyl and the potentially genotoxic substance phosphine (A. 04)
5. Active substances meeting the criteria for endocrine disruption: bruprofezin, cyprodinil, fludioxonil, and fenoxaprop-P-ethyl (A. 05)
6. Pendimethalin (A. 06)

1. **Draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of active substances including the reprotoxic and PFAS flurochloridone, the PFAS diflufenican and the suspected endocrine disruptor difenoconazole (B.02)**

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

- **Diflufenican** is listed as a candidate for substitution due to its high toxicity to aquatic organisms and its extreme persistence (meeting two of the PBT criteria). Its approval should have ended in December 2018, yet it has been repeatedly prolonged without adequate justification. This continued extension is deeply problematic, as diflufenican is a **PFAS (containing a C-CF_3 group) and a known source of trifluoroacetic acid (TFA)**, as confirmed by the Danish GEUS report. According to the report, diflufenican not only degrades into TFA in soil but also contributes to the TFA groundwater contamination, including above the legal limit of 0.1µg/L for some uses. However, the extent of diflufenican's ability to break down into TFA and contaminate groundwater is likely to be significantly underestimated due to the extreme persistence of the substance. With TFA now proposed for classification as toxic to reproduction, and with widespread TFA pollution already documented, prolonging diflufenican's approval is incompatible with the EU pesticide regulation. The latter clearly requires that pesticides and their metabolites must have harmful effects on human health or groundwater, and that the latest scientific evidence must guide decision-making.

- **Flurochloridone** is also listed as a candidate for substitution, with its approval originally due to expire in May 2021. Despite this, its authorisation has been prolonged, even though the substance is **classified as toxic for reproduction (category 1B)**. This classification fulfills a clear 'cut-off' criterion under the Regulation, meaning flurochloridone should already have been banned in order to protect European citizens, including the most vulnerable groups. Beyond its reproductive toxicity, flurochloridone is also a **PFAS** (containing a C-CF_3 group) with moderate to high persistence. Based on its molecular structure, it is expected to degrade into trifluoroacetic acid (TFA), thereby contributing to long-lasting environmental contamination, including of groundwater. In light of these concerns, and in accordance with the pesticide regulation, which requires that substances meeting cut-off criteria and posing risks to human health or groundwater must not be approved, there is a clear obligation to ban flurochloridone without further delay.

- The broad-spectrum azole fungicide **difenoconazole** is approved as a candidate for substitution. Independent scientific studies provide overwhelming evidence of its endocrine activity and associated adverse health effects. Under the Regulation, this

evidence should have led to a clear hazard assessment and the non-renewal of the substance, rather than its repeated prolongation on the EU market. Moreover, difenoconazole generates several metabolites, including 1,2,4-triazole (1,2,4-T), which is classified as reprotoxic (category 1B) due to its adverse effects on fertility. The presence of such a metabolite poses a particular concern for human health, especially for vulnerable groups, and further reinforces the need to end the continued approval of difenoconazole. Finally, difenoconazole is one of the conazole substances effective against *Aspergillus fumigatus*, a saprobic fungus that can cause allergic syndromes, chronic pulmonary aspergillosis, and acute invasive aspergillosis in humans. Unfortunately, over the past decades, antifungal resistance in patients has emerged, and the use of conazoles in agriculture is a major driver of this problem. Since conazoles play a critical role in antifungal therapy for treating aspergillosis in patients, their phase out in agriculture should be a priority. Resistant crop varieties are available; therefore, the European Commission's failure to promote their use and stop the use of conazoles in agriculture is incomprehensible. Particularly considering the OneHealth approach collaboration of the European agencies EFSA/ECHA/JRC.

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.

2. **Draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2023/564 as regards the transfer into electronic format of the records of plant protection products kept by professional users (B. 03)**

Implementation of Regulation (EU) 2023/564 (electronic record keeping of pesticides):

PAN Europe is opposed to the proposal of the Commission to allow a 1-year delay in the electronic registration of pesticides, through amending Implementing Regulation (EU) 2023/564 adopted in context of the SAIO Regulation (EU) 2022/2379. Electronic record-keeping of pesticide use was made mandatory from 1 January 2026, providing ample time for implementation. Digital pesticide use data are long overdue, and pivotal to effectively monitor pesticide use and risk, and to reduce administrative burden. Through European citizens' initiatives, consultations, an IPSOS opinion poll, the Conference for the Future of Europe and EU Barometers and petitions, citizens have expressed loudly that pesticides pose a major societal concern. Ensuring availability of digital pesticide use data is of major importance in order to identify pesticides-intensive crops, to focus attention on knowledge transfer on alternatives as well as research on alternatives for these crops. Therefore, we call upon you to vote against delaying the electronic registration of pesticides for one year.

3. **Draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the PFAS flutolanil (C.06)**

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 (-CF_3) 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. As explained above,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 metabolites[1] and in some cases surpasses even the 10 µg/L threshold for non-relevant metabolites in groundwater[2]. 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 generations. 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.

4. **EFSA conclusions on the PFAS active substance penoxsulam, the reprotoxic substance halosulfuron-methyl and the potentially genotoxic substance phosphine (A. 04)**

a) **Penoxsulam**

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

[1] Austria, Denmark
[2] Germany, Sweden, Switzerland.

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 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 a carbon other than the one forming TFA leading to no TFA detection, 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 µg/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**.

b) Halosulfuron-methyl

Halosulfuron-methyl was approved from 01/10/2013 until 30/09/2023 and its approval period has since been prolonged. This is unacceptable, as since 2017, halosulfuron-methyl has been classified as toxic for reproduction, category 1B. According to Annex II of Regulation 1107/2009, point 3.6.4, an active substance shall not be approved if it meets this classification except in very limited circumstances: either if human exposure is negligible, or under Article 4(7) if a derogation is justified by a serious plant health threat that cannot be controlled by other means, including non-chemical alternatives. In this case, the applicant requested a derogation under Article 4(7) for two uses (rice and maize) across five Member States in the context of EFSA peer review. However, EFSA concluded that a wide range of non-chemical alternatives are available,

and in many cases, a combination of chemical and non-chemical methods is feasible. This directly demonstrates there is no justification for the derogation.

Furthermore, the toxicological reference values (ADI, ARfD, AOEL, AAOEL) for halosulfuron-methyl cannot be considered valid, as the endocrine disruption assessment remains inconclusive (EAS-mediated parameters insufficiently investigated due to data gaps).

It is highly worrying that a substance meeting the cut-off criteria for reproductive toxicity has remained approved for so long, despite evidence since 2017 that the legal conditions for approval were no longer met.

In line with the Pesticide Regulation, we call on you to support the **non-renewal of halosulfuron-methyl.**

c) Phosphine

EFSA conclusions on phosphine peer review raise important concerns and preclude the renewal of the substance in light of the evidence for its clastogenicity. This conclusion is based on *vitro, in vivo* (somatic cells), and *in vivo* human biomonitoring studies. No threshold-based mode of action has been identified, and consequently, no toxicological reference value could be established. Phosphine genotoxic potential has been recognised as a critical area of concern by EFSA. As a result, phosphine does not meet the requirements for renewal.

In line with the Pesticide Regulation, we call on you to urgently support the **non-renewal of phosphine.**

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

As highlighted in our previous letters to SCoPAFF , 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, buprofezin, cyprodinil, fenoxaprop-P-ethyl and fludioxonil, cause harmful effects on human health -particularly vulnerable groups- 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 show that this 'negligible exposure' condition was not demonstrated for these substances. Moreover, as the legal requirements under Article 4(7) for exceptional approval were not satisfied in time by applicants, renewal under this derogation is not permissible for any of these four substances.

In our letter of 23 June 2025, we expressed our deep concern to the Commission regarding the PAFF committee's repeated 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**.

6. Pendimethalin (A. 06)

We wish to express our consternation regarding the handling of the confirmatory information procedure for pendimethalin. This substance, approved as a candidate for substitution due to its toxic and persistent properties, should have been recognised as bioaccumulative since 2021. Consequently, it should have been subject to a ban in line with point 3.7 of Annex II of Regulation 1107/2009, which forbids the approval of substances meeting the PBT criteria[3].

We firmly deplore the decision to close the confirmatory information procedure and to await the outcome of the assessment of the proposal to classify pendimethalin as PBT before taking any action. The confirmatory information submitted in December 2018, and published by EFSA in November 2021, already demonstrated that the BCF value for *Lepomis macrochirus* exceeded the 2,000 L/kg threshold for a "B" classification. It is unacceptable that the applicant's decision to submit additional, non-requested BCF studies for four other species, all below 2,000 L/kg, seemingly in an attempt to downplay the significance of the original finding was accepted. This manoeuvre should not have caused the substantial delays or inaction that followed. The European Commission's approach should have been fully aligned with ECHA's 2017 Guidance on REACH Chemical Safety Assessment, which clearly states that, in the presence of multiple BCF values, the highest valid BCF value must be considered.

[3] See previous communication on this matter.

We therefore call for the **immediate withdrawal of the approval of pendimethalin,** based on the confirmatory information, and in accordance with Article 21 and point 3.7 of Annex II of Regulation 1107/2009.

Thank you in advance for your consideration of these matters.

Sincerely yours,

On behalf of PAN Europe
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