Pesticide Action Network Europe

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

Brussels, 8th December 2025

Subject: EU Standing Committee on Plants, Animals, Food and Feed (SCoPAFF); 10-11 December 2025; position of Pesticide Action Network (PAN) Europe

Dear Members of the SCoPAFF committee,

On 10 to 11 December, 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) 2023/564 as regards the transfer into electronic format of the records of plant protection products kept by professional users (B. 01)
2. Draft Commission Implementing Regulation (EU) extending the approval periods of the active substances including boscalid, esfenvalerate, fluazifop-P, fluazinam, fluometuron, fluopyram, flutolanil, penoxsulam, pyrimethanil (B02)
3. Draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance **flutolanil** (C.01)
4. Draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance **buprofezin** (C05)
5. Draft Commission Implementing Regulation (EU) concerning the renewal of the approval of the active substance **mecoprop-P** (C06)
6. EFSA conclusions on the PFAS active substance **penoxsulam**, the reprotoxic substance **halosulfuron-methyl** and the potentially genotoxic substance **phosphine** (A. 04)
7. Active substances meeting the criteria for endocrine disruption: **cyprodinil, fludioxonil,** and **fenoxaprop-P-ethyl** (A. 05)
8. Confirmatory information for **Pendimethalin** (A06)
9. Technical guidance on the assessment of negligible exposure to an active substance, safener or synergist in a plant protection product under realistic conditions of use (A07.3)

1. **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. 01)**

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.

2. **Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances including boscalid, fluazifop-P, fluazinam, fluometuron, fluopyram, flutolanil, penoxsulam, pyrimethanil (B02)**

The legality of the automatic and repeated extensions of the approvals of active substances has been previously questioned by PAN Europe and other NGOs, through requests for internal review, which the Commission has rejected. In a recent judgement[1] of three Cases (Cases T-412/22, T-94/23, T-565/23) against the Commission, brought before the General Court of the European Union by PAN Europe, Pollinis France and Aurelia Stifing, respectively, the Court sided with the NGOs. The General Court clarified that such extensions must be exceptional and temporary in nature and not systematic, as well as tailored to the concrete progress of the risk assessment. Furthermore, the Court calls upon the Commission to assess objectively and concretely, the role of the applicant in the delays occurring in such procedures, and whether it contributed to the delay by providing data of inadequate quality.

Boscalid.
One of the cases brought to the General Court was specifically on the active substance boscalid, an SDHI fungicide, whose authorisation period has been extended six times since 2018, and has therefore been kept in the market for an additional seven years instead of its original 10-years approval period (2008-2018). According to documents obtained by Pollinis, EFSA had to carry 122 additional requests, after the renewal application dossier was

[1] https://curia.europa.eu/jcms/upload/docs/application/pdf/2025-11/cp250143en.pdf

considered admissible by the Rapporteur Member State (Slovakia), because of data gaps.[2] Therefore, the Commission's proposal to extend its authorisation for yet another year is unjustifiable and contradicts the Court's judgement. This is further supported by evidence indicating that boscalid is an endocrine disruptor and toxic to bees. Already in 2015, the Commission's screening study demonstrated that, based on the available scientific studies and knowledge at the time, boscalid was fulfilling the criteria to be an endocrine disruptor.[3] Data requirements Regulation 283/2013, already provided the requested studies for endocrine disruptors, but the applicant failed to provide them in the renewal application dossier. When finally the scientific criteria to identify endocrine disruptors were adopted in 2018, EFSA requested the missing studies and provided an exceptionally long 'stop the clock' period of 14-08-2019 to 31-01-2025. It is incomprehensible how, after all this delay, an additional confirmatory data request was granted in October 2025. EFSA should have concluded that boscalid is an endocrine disruptor based on the dossier studies, as well as the scientific criteria and therefore does not fulfil the criteria to be reapproved.

Fluazifop-P, fluazinam, fluometuron, fluopyram, flutolanil & penoxsulam.

PAN Europe is concerned about the Commission's proposal to extend the authorisation period for these six pesticide substances, since they fall under the OECD definition of PFAS (contain C-CF3). Moreover, based on their molecular structure, they can degrade into trifluoroacetic acid (TFA), a very persistent, mobile and toxic contaminant thereby contributing to the long-lasting environmental contamination, including of groundwater and food. TFA is currently going under hazard assessment to be classified as toxic to reproduction Category 1B, Persistent, Mobile and Toxic (PMT), as well as very persistent and very mobile (vPvM). Based on new long-term toxicity studies from 2021 and 2023, TFA causes reproduction and developmental toxicity, such as skeletal and eye malformations in rabbit foetuses, as well as adverse effects on thyroid, sperm quality, and immune response. TFA also causes liver toxicity, as it has been previously demonstrated. Combined, these effects raise alarms about the prevalence of TFA in groundwater and food, and require immediate action to ban all TFA emitters, and provide the high level of protection foreseen by Regulation (EC) 1107/2009.

Fluazifop-P and fluazinam produce >0.1 µg/L TFA in groundwater as it was confirmed in a recent report by Denmark[4]. Moreover, Bayer's application for renewal of fluopyram shows that almost all uses of the substance lead to exceedance of the 0.1 µg/L legal limit. Taken together, these data have led the Danish authority to withdraw all pesticide products that contain them in accordance with Article 44.

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[2] Pollinis, 2023. https://www.pollinis.org/admin/wp-content/uploads/2023/07/pollinis-report-eu-endless-extensions-system-threatens-biodiversity.pdf

[3] European Commission, 2015. Screening of available evidence on chemical substances for the identification of endocrine disruptors according to different options in the context of an Impact Assessment. Contract SANTE/2015/E3/SI2.706218

[4] TriFluPest - Miljøstyrelsen

In light of these concerns, and in accordance with the pesticide Regulation (EC) 1107/2009, 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 these PFAS pesticides without further delay.

We call on you to **reject** the Commission's proposal to **prolong the approval period of a series of harmful active substances.**

3. Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance flutolanil

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[5] and in some cases surpasses even the 10 µg/L threshold for non-relevant metabolites in groundwater[6]. An October 2025 study[7] has provided the first quantitative estimation of TFA emissions leaching into groundwater as a direct result of crop applications of 24 EU-approved PFAS pesticides, including flutolanil. For flutolanil, when representative uses on flowers and potatoes were considered, the resulting TFA leaching potential was estimated to be high (≥ 10 µg/L) according to the FOCUS modeling approach.

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

[5] Austria, Denmark
[6] Germany, Sweden, Switzerland.
[7] Trifluoroacetate leaching potential from fluorinated pesticides: an emission estimation and FOCUS modelling approach | Environmental Sciences Europe

substances, including flutolanil, constitute a clear risk for citizens and groundwater and should be banned.

We call on you to **support** the Commission's proposal for **non-renewal of flutolanil.**

4. **Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance buprofezin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (C05)**

PAN Europe welcomes the proposal for non renewal of the approval of buprofezin, which has been identified as an endocrine disruptor for human health by EFSA in its peer-review conclusions published in April this year. The substance was found to disrupt the Hypothalamic-Pituitary-Thyroid (HPT) axis, causing adverse effects on thyroid indicated by alternations in thyroid weight and thyroid histopathology. As substances that alter thyroid function may result in neurodevelopmental toxicity, the use of this substance should stop immediately. Therefore we disagree with providing the maximum grace period of 6 months and an additional year, which in line with Article 20 Regulation (EC) 1107/009 should be given only to non approvals of substances that do not concern the protection of health and the environment.

We call on you to **support** the Commission's proposal for **non-renewal of buprofezin.**

5. **Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the renewal of the approval of the active substance mecoprop-P**

In October 2023, EFSA published its updated peer review on mecoprop-p following its endocrine disruption assessment. Based on these conclusions, mecoprop-p cannot be considered to meet the approval criteria of Regulation (EC) 1107/2009 with regard to the critical area of concern identified by EFSA in 2023. The predicted exposure to residents is above the AOEL for children entering treated areas (75th percentile), even by applying a buffer strip of 10 m and a drift reduction during application. This critical area of concern, which indicates that the conditions set out in Article 4 of Regulation (EC) 1107/2009 are not met, particularly regarding the provisions of the Regulation aiming to ensure that products placed on the market and their residues *"shall not have any harmful effects on human health, including that of vulnerable groups*" (Recital 24; Article 4(2) & (3)). Moreover, mecoprop-p is classified as very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) as well as harmful if swallowed and causing serious eye damage under Regulation

(EC) 1272/2007. Therefore, it cannot be concluded that the use of the substance does not cause any harm to human health or does not have any unacceptable effects on the environment. Nevertheless, the approval of mecoprop-p has been repeatedly extended for a total of 9 years and a half. It is high time that citizens, including agricultural workers, and the environment stop being exposed to this hazardous substance.

We call on you to **reject** the Commission's proposal to renew mecoprop-p.

6. 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 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.**

7. Active substances meeting the criteria for endocrine disruption: cyprodinil, fludioxonil, and fenoxaprop-P-ethyl

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. We regret to see that only for buprofezin the Commission is presenting a non-renewal, while the substances concerned - cyprodinil, fenoxaprop-P-ethyl and fludioxonil- are still under point A, even though it has been identified that they may 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**.

8. Confirmatory information for Pendimethalin (A06)

We wish to reiterate our profound concern regarding the handling of the confirmatory information procedure for pendimethalin and strongly oppose the decision to close this procedure without initiating any action to withdraw the substance. This substance, already approved as a candidate for substitution due to its toxic and persistent properties, should have been recognised as bioaccumulative following the extensive discussions on its bioaccumulation

potential that began in 2019. Consequently, it should have been subject to a ban in accordance with point 3.7 of Annex II of Regulation 1107/2009, which prohibits the approval of substances meeting the PBT criteria.

This position has been further reinforced by EFSA's conclusions of June 2023, following the assessment of confirmatory information, indicating that pendimethalin may be considered a persistent (P), bioaccumulative (B), and toxic (T) substance. Meanwhile, Sweden has submitted a dossier to ECHA for the harmonised classification of pendimethalin as a PBT substance.

We firmly deplore the decision to close the confirmatory information procedure without reaching a conclusion on the bioaccumulation properties of pendimethalin and instead to await the outcome of the assessment of the proposal to classify pendimethalin as PBT before taking any action.

We therefore call on you t**o establish pendimethalin as bioaccumulative, oppose the current renewal review proposal and to request to initiate its withdrawal procedure**.

9. Technical guidance on the assessment of negligible exposure to an active substance, safener or synergist in a plant protection product under realistic conditions of use (A 07.3)

PAN Europe reiterates that the concept of negligible exposure is very narrow and applies only to highly specific conditions, such as the use of pesticides in closed systems that prevent human contact and where residues in food remain below the default limit of determination (LOD). It should therefore not be used to authorise substances that are carcinogenic, toxic to reproduction, or endocrine disruptors, as any exposure to these substances, even minimal, would undermine the objectives of Regulation (EC) 1107/2009, which seeks to ensure a high level of protection. The use of protective equipment should not be used to establish negligible exposure, as this is neither demonstrated nor monitored. Furthermore, negligible exposure for non-target organisms remains to be defined. We invite you to read PAN Europe's position on negligible exposure.

Thank you in advance for your consideration of these matters.

Sincerely yours,

On behalf of PAN Europe
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