Pesticide Action Network Europe

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

Brussels, 8 May 2025

**Subject**: EU Standing Committee on Plants, Animals, Food and Feed (SCoPAFF); 14-15 May - position of Pesticide Action Network (PAN) Europe

Dear Members of the SCoPAFF committee,

On May 14th and 15th, 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. We kindly request that you give these matters your careful attention.

**Agenda issues**

1. Draft Commission Regulation (EU) repealing Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards **labelling requirements for plant protection products** (B.01)
2. Draft Commission Implementing Regulation (EU) renewing the approval of the reprotoxic active substance **quinolin-8-ol** as a candidate for substitution (B.02)
3. Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the PFAS active substance **flutolanil** (C.06)
4. Active substances meeting the criteria for endocrine disruption: **fludioxonil, bruprofezin** (A. 04), **fenoxaprop-P-ethyl, cyprodinil** (A. 05)

1. **Draft Commission Regulation (EU) repealing Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products (B.01)**

PAN Europe welcomes the European Commission's draft Regulation aimed at updating labelling obligations for plant protection products. This update is essential to ensure consistency in plant protection product labelling across Member States and to enhance risk communication for end users. While PAN Europe considers the European Commission's draft Regulation generally satisfactory, we have identified several areas of concern that weaken the quality of risk communication. Our organisation supports that toxic pesticides should not be used in agriculture; hence, for those currently in use, clear and accurate labelling of their hazardous properties is essential to provide true information about the risks of using these pesticides to end users. We share our exhaustive feedback with the Commission during the public consultation[1].

2. **Draft Commission Implementing Regulation (EU) renewing the approval of the active substance quinolin-8-ol as a candidate for substitution (B.02)**

PAN Europe strongly urges the Committee members to oppose the Commission's proposal to renew quinolin-8-ol as a candidate for substitution for use in permanent greenhouses *via* a closed transfer system. This highly hazardous substance does not meet the approval criteria under the Pesticide Regulation 1107/2009, as its continued use poses an unacceptable risk to human health and the environment. Quinolin-8-ol (8-hydroxyquinoline) has been classified as presumed to "damage the unborn child" (toxic for reproduction 1B) since 2015. The Pesticide Regulation clearly establishes that reprotoxic substances cannot be approved in the EU unless negligible exposure to humans can be demonstrated under realistic conditions of use (Article 4(1), point 3.6.4 of Annex II). This exemption must be interpreted restrictively to ensure high protection standards, meaning negligible exposure must be demonstrated for all exposure groups through an objective, robust, and comprehensive dataset. However, EFSA's peer review from March 2024 reveals that these conditions have not been met for quinolin-8-ol due to a lack of reliable data. Key shortcomings in the assessment include:

- **Workers and operators:** The applicant's field study assessing non-dietary exposure for operators and workers had multiple limitations and was considered only 'supportive' evidence for negligible exposure. EFSA deemed it non-reliable for quantitative risk assessment. Yet, this unreliable study was the primary basis for concluding negligible exposure for workers and bystanders. Even with an additional uncertainty factor of 10, there is insufficient confidence that workers and operators will be protected from this reprotoxic substance.

[1] Feedback from: Pesticide Action Network Europe (PAN Europe)

- **Bystanders and resident children:** The non-dietary exposure assessment for bystanders and resident children could not be finalised due to missing data for the representative use. Based on the best available data (spray application), EFSA found that exposure to quinolin-8-ol vapours exceeds the negligible exposure threshold (120% of the Acceptable Observed Effect Level). While drip irrigation might reduce exposure, no field data confirm that bystanders' and residents' exposure would be negligible. This is particularly alarming as it affects vulnerable populations, including pregnant women and children.

Moreover, we consider that a substance cannot be renewed with the condition that its use will result in negligible exposure for all exposed groups if no harmonised guidance has yet been adopted. In fact, it remains unclear on what methodological basis EFSA, and in the future Member States issuing authorisations, can conclude that negligible exposure is achieved. We are aware that work on the guidance document is ongoing and have submitted our feedback to the Commission in the context of a consultation. However, we note that this guidance document still gives rise to major divergences of views and has not yet been adopted by the Member States. Moreover, permanent greenhouses are not entirely closed systems, as emissions into the environment may still take place[2], which is not currently assessed by Member States. Proceeding with the renewal of quinolin-8-ol under these circumstances is premature and fails to align with the high protection standards required by the Pesticide Regulation 1107/2009.

Without action from Member States to reject this proposal, quinolin-8-ol will remain on the market despite its clear failure to meet approval criteria. **We call on you to strongly oppose the Commission's proposal for renewal, support a non-renewal decision, and demand the immediate withdrawal of products containing quinolin-8-ol from the EU market, in line with Article 20(2,3) of Regulation 1107/2009.**

[2] PAN Europe, 2023. It rains pesticides from greenhouses https://www.pan-europe.info/resources/reports/2023/12/it-rains-pesticides-greenhouses-end-myth-greenhouses-are-releasing

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 (C.06)**

On 25 April, we shared with you, via the European Commission, our letter[3] introducing our latest report, *Message from the Bottle*[4], revealing a significant rise in concentrations of trifluoroacetic acid (TFA) in European wines in recent years. The report found TFA in all 39 recently produced wines from 10 European countries, with concentrations reaching up to 320 micrograms per litre (µg/l) and an average of 122 µg/l. These findings once again highlight the urgent need to phase out sources of this significant yet often overlooked pollutant, particularly PFAS pesticides, such as flutolanil.

**We therefore strongly urge 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 carbon-bound perfluorinated methyl group (-$CF_3$). It has been identified as persistent (P) to very persistent (vP) by EFSA. Moreover, due to its molecular structure, flutolanil eventually breaks down into TFA, contaminating soils, crops and water resources. TFA is an ultra-short PFAS degradation product of -$CF_3$ pesticides, which is considered suspected of being toxic for reproduction by pesticide producers (e.g. Bayer), i.e. which may "damage the unborn child" and is currently being assessed by ECHA to be classified as Category 1B (presumed reprotoxic substance). This means TFA is a 'relevant' metabolite, according to Article 3, point 32 of Regulation (EC) No 1107/2009. TFA is also highly persistent, mobile, and soluble in water. It routinely exceeds the 0.1 µg/L limit for relevant metabolites in groundwater, and in some cases surpasses even the 10 µg/L threshold for non-relevant metabolites[5]. 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[6]. 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 consumers and groundwater and should be banned.

4. **Active substances meeting the criteria for endocrine disruption: fludioxonil, bruprofezin (A. 04), fenoxaprop-P-ethyl, cyprodinil (A. 05)**

According to Article 4 of Regulation 1107/2009, an active substance shall only be approved if it may be expected, taking into account the approval criteria set out in points 2 and 3 of Annex II,

[3] Call for a ban of the PFAS active substance flutolanil and the withdrawal of national authorisations of PFAS pesticides | PAN Europe
[4] Message from the bottle | PAN Europe
[5] Austria, Denmark, Germany, Sweden, Switzerland.
[6] The Global Threat from the Irreversible Accumulation of TFA | Environmental Science & Technology

that products containing the active substance and their residues have no harmful effects on human health, including vulnerable groups, and no unacceptable effect on the environment. Points 3.6.5 and 3.8.2 of Annex II specify that a substance shall only be approved if it is not considered to have endocrine-disrupting properties that may cause adverse effects in humans or non-target organisms, unless the exposure is negligible. EFSA's conclusions on the peer review of fludioxonil, bruprofezin, fenoxaprop-P-ethyl, and cyprodinil clearly indicate that these substances do not comply with these requirements.

**Fludioxonil**

On 4 November 2024, EFSA published its conclusion on the peer review of fludioxonil, a candidate for substitution. It concluded that fludioxonil meets the **endocrine disruption criteria for the EAS-modalities for humans and non-target organisms**. Namely, fludioxonil was found to decrease testosterone synthesis and increase estradiol, leading to delayed sexual maturation, decreased anogenital distance in males and increased oestrus cycle in females. These conclusions for humans also apply to wild mammals as non-target organisms.

Furthermore, EFSA noted that **fludioxonil and most of its metabolites are substances that meet the OECD definition of PFAS** based on their chemical structures (–$CF_2$–). In a soil laboratory study, fludioxonil was found to be very persistent, raising further concerns about its long-term impact on human health and the environment. This identification of fludioxonil as PFAS alone justifies a ban, in alignment with the EU's commitment to phase out these hazardous "forever pollutants." The fact it is also an endocrine disruptor underscores the urgency to remove it as soon as possible from the market.

Lastly, EFSA could not finalise several crucial aspects of fludioxonil's risk assessment, including its consumer risk assessment and its groundwater exposure assessment. Meanwhile, fludioxonil was the **most frequently detected candidate for substitution in European fruit** between 2009 and 2019, according to data from the EU Multiannual Control Programme analysed by PAN Europe, confirming European consumers' exposure to this chemical.

**Fenoxaprop-P-ethyl**

According to EFSA's conclusions published on 13 November 2024, fenoxaprop-P-ethyl is an **endocrine disruptor for humans through the A-modality**. Specifically, it was shown to induce changes in the weights of the prostate, epididymis, and testes, along with alterations in testicular weight.

**Cyprodinil**

EFSA's conclusions of 6 February 2025 show clear endocrine-mediated effects of cyprodinil on female and male reproductive health. In humans, cyprodinil was found to induce delayed sexual maturation and decrease ano-genital distance (AGD). This conclusion was considered to be relevant for wild mammals and to generate adverse consequences on reproductive performance. In fish, cyprodinil showed a pattern of endocrine effects, i.e. increase in male vitellogenin, a change in female gonad histology and decreased fecundity and fertilisation

success. Therefore, cyprodinil was considered to meet the **endocrine disruption criteria for the EAS-modalities** for humans and wild mammals and other non-target organisms.

Furthermore, EFSA identified as critical areas of concern a high long-term risk to mammals and a high risk to aquatic organisms for all representative uses.

**Buprofezin**

Bruprofezin meets the **endocrine disruption criteria for the T-modality** according to EFSA conclusions of 24 April 2025. The substance was found to disrupt the Hypothalamic–Pituitary–Thyroid (HPT) axis, generating changes in thyroid weight and thyroid histopathology. These adverse effects were considered to apply to humans and wild mammals.

The approvals of these endocrine-disrupting substances were initially set to expire in 2017 (cyprodinil), 2018 (fludioxonil and fenoxaprop-P-ethyl) or 2021 (buprofezin) but have been extended multiple times due to several delays in risk assessment. This means that farmers, residents of agricultural zones and European consumers continue being exposed to these harmful chemicals. Without further delay and in line with points 3.6.5 and 3.8.2 of Annex II of Regulation 1107/2009 as well as Article 13(5) of Regulation 844/2012, stating that *"Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission shall not be taken into account"*, we urge Member States to support the **swift non-renewal of bruprofezin, cyprodinil, fenoxaprop-P-ethyl and fludioxonil.**

From beforehand, thank you for your consideration.

Sincerely yours,

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