Pesticide Action Network Europe

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

Brussels, 4 March 2025

Subject: EU Standing Committee on Plants, Animals, Food and Feed (SCoPAFF); 11-12 March - position of Pesticide Action Network (PAN) Europe

Dear Members of the SCoPAFF committee,

On March 11th and 12th, you are invited to the EU Standing Committee on Plants, Animals, Food and Feed to discuss and potentially adopt opinions on several European Commission's 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 Implementing Regulations (EU) concerning the non-renewal of the approval of the active substances **flufenacet** (B. 02) and **flutolanil** (C. 06)
2. Draft Commission Implementing Regulation (EU) renewing the approval of the active substance **quinolin-8-ol** as a candidate for substitution (B.06)
3. **Fludioxonil** (A. 04) and **fenoxaprop-P-ethyl** (A. 05)
4. Draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances (...) fludioxonil, flufenacet, flutolanil and others (B.09)
5. AOB: new findings on the neurotoxic effects of **deltamethrin**
6. Implementation of Implementing Regulation (EU) 2023/564 and Regulation 2022/2379 (SAIO)

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1. **Draft Commission Implementing Regulations (EU) concerning the non-renewal of the approval of the active substances flufenacet (B. 02) and flutolanil (C. 06)**

PAN Europe strongly urges the SCoPAFF Members to adopt the European Commission's proposals for non-renewal of flufenacet and flutolanil. The identification of these substances as Per- and polyfluoroalkyl substances (PFAS) alone justifies their immediate withdrawal from the EU market, in alignment with the EU's commitment to phase out these hazardous "forever pollutants."

Both flufenacet and flutolanil meet the OECD definition of PFAS and break down into trifluoroacetic acid (TFA), an ultra-short PFAS contaminating water resources across Europe, including groundwater and drinking water. TFA is highly persistent, mobile, accumulating and exceeding legal contamination thresholds for groundwater in numerous European cases[1]. This is particularly alarming as TFA is now to be classified as toxic for reproduction, making it toxicologically relevant.

For flufenacet, EFSA has clearly concluded that its use results in TFA levels surpassing both the 0.1 µg/L legal limit for relevant metabolites and the 10 µg/L limit for non-relevant metabolites in groundwater.Regarding flutolanil, EFSA's peer review has identified it as a persistent (P) to very persistent (vP) substance on top of generating TFA.

In addition, flufenacet has been identified as an endocrine disruptor for humans and non-target organisms, meeting cut-off criteria under the Pesticide Regulation 1107/2009 (Article 4(1), points 3.6.5 and 3.8.2 of Annex II). EFSA has concluded that flufenacet alters the thyroid-stimulating hormone, leading to changes in thyroid weight and thyroid histopathology. This T-mediated endocrine disruption of flufenacet has also been suspected of causing the developmental neurotoxic effects observed in a DNT study.

Without diligent action by Member States to support the Commission's proposals for non-renewal of these two substances, their approval period risks being extended one more time (please refer to agenda item B.09). Such a prolongation would be unacceptable given the clear indications that these substances have harmful effects on human health and groundwater, and unacceptable effects on the environment. In addition, the approval period for these substances has already been systematically and consecutively extended for many years (11 years for flufenacet, and 6 years for flutolanil). To ensure that the objective and requirements of Pesticides Regulation 1107/2009 are complied with, we urge you to adopt the two proposals B. 02 and C. 06 presented by the European Commission at the meeting on March 11 and 12.

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

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2. **Draft Commission Implementing Regulation (EU) renewing the approval of the active substance quinolin-8-ol as a candidate for substitution (B.06)**

PAN Europe strongly urges SCoPAFF 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 approval poses an unacceptable risk to human health. 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.
- **Bystanders and resident children:** The non-dietary exposure assessment for bystanders and resident children could not be finalized due to missing data for the representative use. Based on the best available data (spray application), EFSA found that exposure to quinolin-8-ol vapors 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 harmonized 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. 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.

3. **Fludioxonil (A. 04) and fenoxaprop-P-ethyl (A. 05)**

In a letter dated January 2025, PAN Europe urged the European Commission to swiftly propose the non-renewal of fenoxaprop-P-ethyl and fludioxonil following their identification as endocrine disruptors. The two substances do not comply with the requirements of the Pesticide Regulation 1107/2009, which aim to ensure a high level of protection of human health and the environment.

According to Article 4 of Regulation 1107/2209, 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- that products containing the active substance and their residues have no harmful effects on human health, including that of 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. EFSA's conclusions on the peer review of fenoxaprop-P-ethyl and fludioxonil clearly indicate that these two substances do not comply with these requirements.

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 as laid down in points 3.6.5 and 3.8.2. of Annex II to the Pesticide Regulation 1107/2009. Namely, fludioxonil was found to decrease testosterone synthesis and increase estradiol leading to delayed sexual maturation, decreased anogenital distance in males and increased oestruscycle in females. These conclusions for humans also apply to wild mammals as non-target organisms. Furthermore, EFSA could not finalise several crucial aspects of fludioxonil's risk assessment, including its consumer risk assessment and its groundwater exposure assessment. Fludioxonil was the most often detected candidate for substitution in European fruit between 2009 and 2019 according to data from the EU Multiannual Control Programme analysed by PAN Europe.

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According to EFSA's conclusions, 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, alongside alterations in testicular weight.

The approvals of these two dangerous substances were initially set to expire in 2018, but have been extended to 2025 due to several delays in risk assessment. Without further delay and in line with 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 fenoxaprop-P-ethyl and fludioxonil.

4. **Draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances (...) fludioxonil, flufenacet, flutolanil and others (B.09)**

PAN Europe is highly critical of the systematic practice of the Commission and Member States of extending substances' approval periods because the (re)approval procedure has not been completed within the legal timeframe. Delays in risk assessment and resulting approval prolongations lead to continued exposure to substances for which there is evidence indicating they do not comply with the requirements to protect human health, groundwater and the environment of the Pesticide Regulation 1107/2009. This is shown by the draft Commission Implementing Regulation which concerns:

- Fludioxonil: meets the criteria for endocrine disruption for humans and non-target organisms.
- Flufenacet: meets the criteria for endocrine disruption for humans and non-target organisms, meets the OECD definition of PFAS and breaks down into TFA.
- Flutolanil: meets the OECD definition of PFAS and breaks down into TFA.

We call on Member States to reject this Commission's proposal and proceed to immediate non-approvals of the above-mentioned substances, as developed in items 1 and 3 of this letter.

5. **AOB: new findings on the neurotoxic effects of deltamethrin**

We would like to bring to your attention our letter of 26 January 2025 to the Commission and Member States presenting several key new scientific evidence studies on neurotoxicity caused by the substance deltamethrin. These studies highlight harmful effects of deltamethrin on the brain, particularly during the developing stage, putting at risk the most vulnerable of our population, pregnant women, newborns and children. These effects (loss of memory, learning deficits, autism) were observed at the 'No Observed Adverse Effect Level' (NOAEL) and at

lower levels. We urge the Commission and Member States to immediately start a fast track Article 21 procedure to review these new scientific findings and withdraw the approval of deltamethrin. A similar procedure should be undertaken under the Biocidal Products Regulation 528/2012.

6. **Implementation of Implementing Regulation (EU) 2023/564 and Regulation 2022/2379 (SAIO)**

We would like to highlight the importance to implement without delay the Commission's Implementing Regulation 2023/564, as regards the content and format of the records of pesticides kept by professional users pursuant to Regulation 1107/2009. Regulation (EC) 1107/2009 requires that professional users keep records of pesticides used, and provide this information to competent authorities. The Commission proposed Implementing Regulation 2023/564 to meet the needs of Member States to facilitate existing data keeping obligations and comply with Regulation 2022/2379 on statistics on agricultural input and output (SAIO). To allow sufficient time for practical implementation, electronic data registration should take effect in 2026. It is essential that these Regulations are implemented without delay, given the urgent need for coherent data keeping and monitoring of pesticide use, while also reducing bureaucratic burden for farmers and policy-makers. Electronic registration of pesticide use will benefit member states, farmers, EU citizens, as well as the work of EUROSTAT. Pesticide use has far-reaching impacts on human health, biodiversity and ecosystem services. Ensuring robust digital record-keeping of pesticide use is an essential responsibility of EU and national policy-makers. The need for robust digital data was also underlined in the Outcome of the Strategic Dialogue on Agriculture, in view of an EU-wide sustainability benchmarking system. In addition the EU Vision for Agriculture and Food underlined the importance of robust and improved data gathering, sharing and digitalisation. Here, we would like to refer to our letter sent in December 2024 to EU Ministers of Agriculture, Environment and Health.

From beforehand, thank you for your consideration.

Sincerely yours,

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