

To: members of the PAFF Committee - Section "Phytopharmaceuticals - Legislation"

Brussels, 4 July 2024

**Subject**: Request to oppose the European Commission's proposal to renew captan and 8-hydroxyquinoline, considering the risks for humans and the environment

Dear members of the PAFF committee,

On 10 and 11 July, you are invited to discuss and adopt opinions on several proposals by the European Commission in the EU Standing Committee on Plants, Animals, Food and Feed. In advance of this meeting, we, the 12 undersigned environmental and health organisations of the Pesticide Action Network, are urging you to **oppose the proposals to renew the approvals of the hazardous fungicides captan and 8-hydroxyquinoline**. According to the European Food Safety Authority (EFSA), these two substances do not comply with the Pesticide Regulation's requirements that pesticides shall have no harmful effects on human health and no unacceptable effects on the environment (Regulation 1107/2009).

**Captan** is currently proposed for renewal in open fields, in the absence of a qualified majority on an earlier proposal to restrict its use to permanent greenhouses. This sudden change in the Commission's proposal is in response to political pressure from certain Member States but has no scientific backing and no legal ground. On the contrary, EFSA's conclusions<sup>1</sup> clearly show that captan poses a risk to consumers' health and to wild mammals, fish and aquatic invertebrates as well as non-target arthropods (critical area of concern). This means that no safe use of captan could be established by EFSA considering the approval criteria of the Pesticide Regulation (Article 4), especially for outdoor uses. PAN Europe was already extremely critical of the attempt by the Commission to eliminate the identified high risks to these non-target species by restricting captan use to permanent greenhouses, as there was no actual scientific demonstration by EFSA that these are closed spaces, preventing its emission into the environment. Nevertheless, the new proposal is even more worrying. **A recent statement by** 

<sup>&</sup>lt;sup>1</sup> <u>Peer review of the pesticide risk assessment of the active substance captan | EFSA (europa.eu)</u>

**EFSA** from 2024<sup>2</sup> showed that it cannot be <u>realistically</u> demonstrated that the risks to non-target organisms would be lowered to an acceptable level by implementing risk mitigation measures, as now proposed by the Commission. Ironically, this was acknowledged by the Commission itself when responding to written questions from Members of the European Parliament<sup>3</sup> in May 2024. Moreover, according to a recent case law<sup>4</sup>, the Commission must ensure that such measures are actually (and not theoretically) demonstrated, in order to re-approve a substance. This is not the case for captan. The proposal to restrict captan use outside the flowering stage of the crop and when no flowering weeds are present in the rows of the treated crops, as well as to minimise the drift to areas outside the target surface of the crop cannot seriously be considered as realistic conditions of use and have not been validated by EFSA.

A second concern with regard to captan is that EFSA's new statement highlights a **genuine risk to consumers via drinking water consumption**. This results from the recommendation by the European Chemical Agency (ECHA) to classify captan as toxic for reproduction (category 2). The latter comes on top of its existing classification as carcinogenic (category 2), leading some metabolites to become toxicologically relevant considering their predicted concentration level in groundwaters. Therefore, captan not only poses a risk to non-target organisms but also to humans. This makes the Commission proposal contrary to the Pesticide Regulation whose primary objective is to ensure a high level of protection. This objective must prevail over yields consideration as reminded by the European Court in its case law<sup>5</sup>.

Our concerns then relate to the Commission's intention to renew **8-hydroxyquinoline** for use in permanent greenhouses, thus bypassing the 'cut-off' approach of the Pesticide Regulation for highly hazardous substances. 8-hydroxyquinoline has been classified as presumed to "damage the unborn child" since September 2019 (i.e. **toxic for reproduction 1B**). Moreover, it is classified as being very toxic to aquatic life with long-lasting effects (Aquatic Acute 1/Aquatic Chronic 1), leading to the EFSA conclusion that it poses a high risk to some non-target species. The Pesticide Regulation clearly establishes that reprotoxic substances cannot be approved in the EU unless negligible exposure to humans can be demonstrated in certain conditions of use (Article 4(1), point 3.6.4 of Annex II). In March 2024<sup>6</sup>, EFSA clarified that negligible exposure to humans cannot be demonstrated for 8-hydroxyquinoline in the case of automated drip irrigation in a permanent greenhouse contrary to what the Commission claims. Namely, EFSA pointed out that **for residents and bystanders, the exposure of children to the vapour of 8-hydroxyquinoline is predicted to exceed the threshold for negligible exposure (120% of Acceptable Observed Effect Level). Evidently, negligible exposure cannot be demonstrated for** 

<sup>&</sup>lt;sup>2</sup> <u>Statement on the refined environmental risk assessment and impact of the new classification for captan</u> [EFSA (europa.eu)

<sup>&</sup>lt;sup>3</sup> Parliamentary question | Answer for question E-000758/24 | E-000758/2024(ASW) | European Parliament (europa.eu)

<sup>&</sup>lt;sup>4</sup>Judgement of the General Court of 21 February 2024, *Pesticide Action Network Europe (PAN Europe) v European Commission*, T-536/22, §104.

<sup>&</sup>lt;sup>5</sup> Judgement of the Court of 19 January 2023, *Pesticide Action Network Europe ASBL and Others v État belge*, C-162/21, §48.

<sup>&</sup>lt;sup>6</sup> <u>Peer review of the pesticide risk assessment of the active substance quinolin-8-ol - 2024 - EFSA</u> Journal - Wiley Online Library

these particularly vulnerable groups of the population. More generally, EFSA pointed to the clear weakness of its own risk assessment, which results in a need to cautiously interpret its conclusions for operators and workers:

- The representative use of drip irrigation in permanent greenhouses was not fully represented in the EU-validated models when the latter were used to assess negligible exposure to 8-hydroxyquinoline;
- The field study submitted by the application had several limitations and could only be considered as supportive evidence for negligible exposure but insufficiently reliable for quantitative risk assessment.

Furthermore, we would like to point out that EFSA's assessment of negligible exposure is based on a guidance document by the European Commission that was never scientifically approved by EFSA or politically endorsed by the Member States before being used due to major controversies. Considering the above, we urge you to oppose the renewal of 8-hydroxyquinoline no matter what restrictions on use the European Commission proposes.

Thank you for your prompt action on this highly important matter for human health and the environment.

Sincerely yours,

Angeliki Lysimachou Head of Science and Policy **Pesticide Action Network Europe** 

On behalf of the signatories:

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