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

Brussels, 30 June 2022

Subject: PAFF July meeting (A. 06, point 1) - Confirmation information on Propyzamide - Call upon Member States to reject the amended review report

Dear members of the PAFF committee,

On 14/15 July, during the EU Standing committee on Plants, Animals, Food and Feed (PAFF), you will be invited to endorse the amended review report for the active substance propyzamide presented by the European Commission to continue the approval of the substance. We urge you to reject this review report, which is contrary to articles 1 (3)(4), 4 and 21 of Regulation (EC) No. 1107/2009 and the Guidance Document SANCO/5634/2009, and urge you to call instead for a review and withdrawal of approval of propyzamide in line with article21.

Propyzamide is an herbicide approved as a candidate for substitution from May 2018 to June 2025 in the context of Commission Implementing Regulation (EC) 2018/755. The classification as candidate for substitution is due to its persistent (P) and toxic (T) properties of propyzamide[1]. Additionally, the active substance is classified as suspected carcinogen (Cat.2, H351), acute toxic for aquatic organisms (H400) and toxic for aquatic organisms with long term effects (H410).

[1] In accordance with indent 2, point 4 of Annex IV of Regulation (EC) No. 1107/2009.

In accordance with article 6(f) of Regulation (EC) No 1107/2009, the approval of propyzamide was conditioned to the submission of confirmatory information by the applicant within specific time limits in the following areas: a) toxicological profile of metabolites in significant concentration in primary and rotational crops; b) the soil degradation of metabolites RH-24580; c) effects of water treatment processes on the nature of residues present in surface and groundwater.

Both the technical report and the additional peer review of EFSA on the mammalian toxicology and residues demonstrated that the submitted confirmatory information fails to address all the three points raised in the approval Regulation (EC) No 2018/755. With this result, approval should not be continued. Rather, the submitted confirmatory information demonstrated that due to several of its metabolites (RH-24644 and RH26702), the substance poses an unknown risk to consumers, and that the relevant metabolite RH-24580 is expected to be found in groundwater above the drinking water limit, resulting in an unacceptable risk for consumers[2].

a) Toxicological profile of metabolites in significant concentration in primary and rotational crops

Regarding the two metabolites RH-24644 and RH26702, EFSA experts concluded that *"genotoxic potential could not be ruled out since both are positive mutagenic in vitro (in an AMES test) and inconclusive in vivo (in an in vivo Pig-A gene mutation analysis). Thus, reference values set for propyzamide cannot be applied to these metabolites*." Furthermore, the confirmatory data did not address the data gaps identified for residue field trials. As a result, EFSA highlighted that *"the plant residue definition (...) cannot be finalised and a robust consumer dietary intake calculation cannot currently be conducted*"[3]. Thus, the risks arising from consumers' exposure to these metabolites cannot be assessed, contrary to Regulation (EC) No. 1107/2009.

b) The soil degradation of metabolites RH-24580

Secondly, metabolite RH-24580 has been considered relevant for groundwater, due to the poor assessment of its genotoxicity and due to the classification of Propyzamide as carcinogen Cat. 2. Building on the FOCUS model, the predicted concentration level in groundwater for this metabolite is above the drinking water limit for relevant metabolites of 0.1 µg/L. This exceeding of the legal limit has been confirmed with the confirmatory data provided by the applicant. In accordance with the Guidance Document Sanco/221/2000 on the assessment of the relevance of metabolites in groundwater, an active substance whose relevant metabolite is exceeding the concentration limit of 0.1 µg/L does not meet the criteria for approval of Regulation (EC) 1107/2009[4].

[2] Article 3 (32) provides that metabolites with unacceptable toxicological properties are deemed relevant for the overall approval decision.

[3] EFSA, 2022, Peer review of the pesticide risk assessment for the active substance propyzamide in light of the confirmatory data submitted.

[4] See page 18 of Guidance Document Sanco/221/2000

c) Effects of water treatment processes on the nature of residues present in surface and groundwater

Finally, as no relevant guidance document has yet been prepared on this last point, no data is available to address this point and an assessment is not possible.

As a result of these three points, the confirmatory information has not properly addressed any of the points of concerns raised in the Implementing Regulation (EC) No 2018/755 that would allow the continued approval of propyzamide. Instead, information with regard to the genotoxic potential of some of its metabolites and of unsafe concentration levels in groundwater have shown that the risks posed to consumers is either uncertain or not acceptable.

Therefore, at the end of this confirmatory information procedure and contrary to what the Commission claims, it *cannot* be expected that propyzamide meets the approval requirements set out in Article 4 of Regulation (EC) No 1107/2009. Consequently, the amended review report of propyzamide proposed for endorsement is not compliant with Regulation 1107/2009 and must be reviewed. In accordance with article 21 (3) of Regulation (EC) 1107/2009, where *"the approval criteria provided for in article 4 are no longer satisfied, or the further information required in accordance with article 6(f) has not been provided, a Regulation to withdraw or amend the approval shall be adopted"*. This important provision is reflected in the guidance document SANCO/5634/2009 on confirmatory information, which states that when the confirmatory information fails to address the points raised in the approval Regulation and which conditions it, the active substance approval should be withdrawn or restricted. Article 21 also echoes article 4 (3)(b) of Regulation (EC) 1107/2009 which provides that a substance "*shall have no immediate or delayed harmful effect on human health, including of vulnerable groups (..), directly or through drinking water*", as well as the precautionary principle set out in Article 1(3) of Regulation (EC) 1107/2009.

As it cannot be expected that propyzamide or pesticides containing propyzamide still fulfill the safety requirements laid down in Regulation (EC) No 1107/2009, allowing its continued approval would go against Regulation (EC) No 1107/2009. Therefore, we call you to reject this amended report and to ask instead for the withdrawal of propyzamide in the shortest delay.

We remain at your disposal to exchange in more detail.

Sincerely yours,

Koen Hertoge,
President, Pesticide Action Network Europe

Pauline Cervan,
Toxicologist, Générations Futures