

To: Mr Humberto Delgado Rosa  
Director of Directorate D “Biodiversity”  
European Commission - Directorate-General for Environment

Cc: Mr Aurel Ciobanu-Dordea  
Director of Directorate B ‘Circular Economy’  
European Commission - Directorate-General for Environment



Brussels, 24 November 2023

**Subject: Approved herbicide pendimethalin is a PBT substance**

Dear Mr Delgado Rosa,

With this letter we wish to highlight our concerns regarding the handling of the approval of the active substance pendimethalin by DG for Health and Food Safety (DG SANTE). We respectfully request DG for Environment (DG ENV) to intervene and help obtain the swift ban of this substance meeting the Persistent, Bioaccumulative and Toxic (PBT) criteria of the Pesticide Regulation (EC) 1107/2009.

In accordance with the Pesticide Regulation (EC) 1107/2009, pesticides and their individual compounds shall have no unacceptable effects on the environment (Article 4). Article 4(1) requires that the assessment of an active substance must first establish whether certain approval criteria are satisfied, including those listed under 3.7 of Annex II. Namely, point 3.7.2 of Annex II provides that “*an active substance, safener or synergist shall only be approved if it is not considered to be a persistent, bioaccumulative and toxic (PBT) substance*”. Therefore, if the substance meets the PBT criteria, it cannot be approved. When scientific doubt remains, risk management decisions must be based on the precautionary principle, and the approval of an active substance can be withdrawn (Article 1). In the case of pendimethalin, we observe that these key provisions to ensure the high level of protection of the environment are presently not being respected by DG SANTE.

Pendimethalin was reapproved as a candidate for substitution in 2017 as it fulfilled the criteria as persistent (P) and toxic (T) set out in points 3.7.2.1 and 3.7.2.3 of Annex II to Regulation (EC) 1107/2009. However, in the EFSA’s peer review<sup>1</sup> which preceded this renewal decision, the bioaccumulation (B) potential of the substance could not be excluded. This data gap should have

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<sup>1</sup>[Peer review of the pesticide risk assessment of the active substance pendimethalin | EFSA \(europa.eu\)](https://www.efsa.europa.eu/en/peer-review/active-substance/pendimethalin)  
[Peer review of the pesticide risk assessment of the active substance pendimethalin | EFSA \(europa.eu\)](https://www.efsa.europa.eu/en/peer-review/active-substance/pendimethalin)

led to a non-renewal of the substance. Nevertheless, the Commission renewed the approval of the substance for 7 years and requested the submission of confirmatory information regarding the B potential of pendimethalin referring to Article 6(f) of Regulation (EC) 1107/2009. In particular, the applicant was requested to provide a reliable BCF value for bluegill sunfish (*Lepomis macrochirus*) by 31 December 2018. The submission of this information was crucial to clarify whether the substance's approval is in line with the approval requirements of Regulation (EC) 1107/2009.

The supporting publication<sup>2</sup> in light of the submitted confirmatory data published by EFSA in November 2021, shows that the BCF value for *Lepomis macrochirus* was found to exceed the trigger value of 2,000 L/kg for a B classification. It was further highlighted that this BCF value might underestimate the degree of the bioaccumulation potential of pendimethalin as the Total Organic Carbon (TOC) of the exposure medium was artificially increased by adding humic acid. This is contrary to OECD TG 350<sup>3</sup>, which recommends keeping the TOC at the lowest possible level to avoid sorption of test particles to the organic particles, thus reducing chemical bioavailability. Furthermore, the applicant decided to provide non-requested BCF studies for four other species, with BCF below 2000 L/kg in an attempt to downplay the findings of the requested study. In the meantime, the Environmental Protection Agency of New Zealand acknowledged the B potential of pendimethalin in fish (BCF 5100 L/kg)<sup>4</sup>.

BCF studies for *Lepomis macrochirus* are frequently used as the only species to decide on the B classification of active substances. Moreover, in the presence of several BCF values, the highest valid BCF value should be considered, in line with ECHA 2017 Guidance on REACH Chemical Safety Assessment<sup>5</sup>. Therefore, based on the existing evidence provided as part of the confirmatory information procedure and in line with the requirements of Regulation (EC) 1107/2009 including the precautionary principle, pendimethalin should be regarded as bioaccumulative and thus as meeting the PBT criteria. Its approval should be withdrawn in accordance with Article 4 (1) to (3), Article 21 and point 3.7.2 of Annex II Regulation (EC) 1107/2009 in the shortest delay.

Instead of a withdrawal of its approval, DG SANTE decided to mandate EFSA and ECHA to give guidance to define BCF for regulatory purposes, in cases where data from more than one species are available. To date, no guidance has been provided and pendimethalin is still approved despite convincing evidence since 2021 that it meets the PBT criteria and therefore pose unacceptable effects on the environment as set out in point 3.7.2.3 of Annex II to Regulation (EC) 1107/2009. PAN Europe strongly regrets the lack of progression of the last two years.

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<sup>2</sup>[Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for pendimethalin in light of confirmatory data - - 2021 - EFSA Supporting Publications - Wiley Online Library](#)

<sup>3</sup>[https://read.oecd-ilibrary.org/environment/test-no-305-bioaccumulation-in-fish-aqueous-and-dietary-exposure\\_9789264185296-en#page7](https://read.oecd-ilibrary.org/environment/test-no-305-bioaccumulation-in-fish-aqueous-and-dietary-exposure_9789264185296-en#page7)

<sup>4</sup>[Chemical Classification and Information Database \(CCID\) | EPA](#)

<sup>5</sup>[https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r11\\_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f](https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f)

In your role of Director of the department in charge of biodiversity protection, we ask you to point out to DG SANTE that its current approach of postponing any decision on the current approval of pendimethalin from one SCoPAFF meeting to the next is undermining the high level of environmental protection required by Regulation (EC) 1107/2009. Moreover, we ask you to urge DG SANTE to propose the withdrawal of the approval of pendimethalin without delay at the SCoPAFF meeting scheduled on 11th and 12th December.

Thank you for your attention to this matter.

On behalf of Pesticide Action Network Europe

Sincerely,

Angeliki Lysimachou  
Head of Science and Policy