EEB and PAN Europe Comments on Transfer ATP regarding harmonised classification of EDC, PBT and vPvB

Follow-up to the 57th CARACAL meeting - 18 March 2026
Agenda item 3: Harmonised classifications - amendments of Annex VI Transfer ATP
15 April 2026

The Commission and ECHA are acknowledged for providing the overview of substances proposed for inclusion in the transfer ATP to the CLP regulation, with harmonised classifications based on EDC, PBT or vPvB properties in accordance with CLP Article 37.7.

We **strongly support the harmonised classification of substances already identified as EDC, PBT or vPvB** under the REACH Regulation, the Biocidal Products Regulation (BPR) or the Plant Protection Products Regulation (PPPR). As these substances have undergone extensive scientific evaluation, their transfer to CLP constitutes merely a procedural step, ensuring consistency and avoiding duplication of hazard assessments across regulatory frameworks. We have a few comments for your consideration.

1) **Transition time:** Considering that the transfer ATP does not introduce new hazard identification but merely reallocates existing classifications into Annex VI of CLP, a shortened transition period of six months is justified. Most substances concerned have been identified as EDC, PBT or vPvB for many years, or at the latest by June 2025, with the regulatory pathway clearly established following the 2024 revision of the CLP Regulation. This has ensured predictability and transparency for stakeholders, and allowed for ample time to anticipate these changes. **A six-month transition period after entry into force of the transfer ATP is sufficient for implementation, as this corresponds to at least 18 months since the latest EDC, PBT, or vPvB identifications**. Extending the transition by a further 18 months would be disproportionate and would unnecessarily delay the effective alignment with harmonised classifications and their practical implementation.

2) **Substances proposed for inclusion**: We **strongly recommend to re-introduce in the transfer ATP the following substances**, that were removed from the initial proposal:
    a. ethiprole (ISO); 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-(ethanesulfinyl)-1H-pyrazole-3-carbonitrile: this entry has been excluded from the Annex VI of CLP as "it has never been approved or notified for approval for the uses in plant protection products under PPPR, therefore it does not meet the criteria of 37(7) CLP to be included in the amendment." We disagree with this decision, and would like you to consider including again the substance in the Annex VI. Please see detailed comments on ethiprole in Annex 1 to these comments. Considering that an approval or non-approval of ethiprole is outside

the scope of the assessment of this substance, and will never take place, we consider it appropriate to be included in the Annex VI, as an ED for human health.

b. 3-iodo-2-propynylbutycarbamate (IPBC); Iodine; PVP-iodine; Medetomidine; and Zineb; identified as EDCs after careful evaluation under the BPR;
c. fludioxonil (ISO); 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile; cyprodinil (ISO); 4-cyclopropyl-6-methyl-N-phenylpyrimidin-2-amine; fenoxaprop-P-ethyl (ISO); ethyl (2R)-2-{4-[(6-chloro-1,3-benzoxazol-2-yl)oxy]phenoxy}propanoate; buprofezin (ISO); (Z)-2-tert-butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one; thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole; identified as EDC after careful evaluation under the PPPR.

These substances should be included in Table 3 of Part 3 of Annex VI to the CLP regulation with a harmonised classification as EDC to avoid unnecessary future duplication of assessments of the endocrine properties and ensure adequate hazard communication and risk management in line with the CLP regulation.

3) **Additional substances:** Strong support is also expressed for the inclusion of additional substances proposed for transfer to Annex VI of the CLP regulation:
   a. substances included in the REACH candidate list, conform CLP Article 37.7, including 1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy] trisiloxane, Decamethyltetrasiloxane, and 1,1'-(ethane-1,2-diyl)bis[pentabromobenzene];
   b. quinoxyfen, (ISO); 5,7-dichloro-4-(4-fluorophenoxy)quinoline based on its identification as PBT and vPvB under the PPPR; and
   c. Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) if containing ≥0.1% w/w 4-heptylphenol, branched and linear (4-HPbl)

These inclusions are consistent with CLP Article 37.7 and would ensure coherence across regulatory frameworks and support effective hazard communication under the CLP framework.

4) Specific comments on both **flufenacet and metribuzin**:

In relation to comments that CARACAL has received on flufenacet and metribuzin, we read that Bayer disagrees with the classification of flufenacet and metribuzin as ED for HH by EFSA, even though this classification is based on the ECHA/EFSA Guidance Document. Both substances cause ED via T-modality; Mode of Action (MoA), adverse effects and a plausible mechanism between the two was found. Therefore, we strongly support the inclusion of flufenacet and metribuzin in Annex VI of CLP. Please see Annex 2 for detailed comments.

Annex 1: Inclusion of ethiprole in Annex VI of CLP

We see that ethiprole has been excluded from the Annex VI of CLP as "it has never been approved or notified for approval for the uses in plant protection products under PPPR, therefore it does not meet the criteria of 37(7) CLP to be included in the amendment."

We disagree with this decision, and would like you to consider including again the substance in the Annex VI, for the following reasons.

The assessment of ethiprole for its ED properties took place in the framework of assessment of the request of CropLife and Bayer to set import tolerance for the non-approved substance ethipriol in rice. According to EFSA, looking at the toxicological profile, it was considered necessary to carry out an assessment of the endocrine disrupting properties (ED) of ethiprole, in line with the 2018 ECHA/EFSA guidance. Additional studies were requested. Following the assessment (EFSA, 2024), EFSA states that the thyroid (T) modality was considered sufficiently investigated and a pattern of T adversity was concluded, (increased thyroid weight and follicular cell hypertrophy observed in several rat studies with different dose regimes and exposure durations) and T endocrine activity, (decrease in serum T4 and increase in TSH observed in short-term toxicity studies in rat). Therefore, ethiprole was found to meet the criteria of endocrine disruption for humans.

The objective of the risk assessment of ethiprole was not to support the decision on approval or not approval of the substance, but on an import tolerance request and establishment of health-based values. This decision was adopted in March 2025[1] by the Standing Committee of Plants Animals Food and Feed. Although the decision was not on the approval or non approval of ethiprole, the guidance document used to carry the assessment is the same as with the risk assessment for approval of active substances, and therefore the scientific methodology doesn't change. Moreover, the methodology has led to a political decision on EU establishment of health-based values.

Considering that an approval or non-approval of ethiprole is outside the scope of the assessment of this substance, and will never take place, we consider it appropriate to be included in the Annex VI, and an ED for human health, and avoid any unnecessary future duplication of the assessment of the endocrine properties of this substance.

[1] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/backend/api/active_substance/download/1510

Annex 2: Detailed Comments on both flufenacet and metribuzin.

In relation to comments that CARACAL has received on flufenacet and metribuzin, we read that Bayer disagrees with the classification of flufenacet and metribuzin as ED for HH by EFSA, even though this classification is based on the ECHA/EFSA Guidance Document. Both substances cause ED via T-modality; Mode of Action (MoA), adverse effects and a plausible mechanism between the two was found (see NOTES for EFSA decision on T-modality). In this regard we would like to provide a few comments, as PAN Europe has followed closely the scientific assessment of these substances.

1) **No re-assessment is required.** The legal obligation introduced under Article 7 (7) to transfer pesticide substances already identified as ED for HH or EnvH under Regulation (EC) 1107/2009 to Annex VI of CLP, aims to avoid duplication of the assessment of hazardous substances and unnecessary use of resources. It should be simple and effective and therefore the inclusion of ED pesticide active substances to CLP Annex VI does not foresee and must not include any additional assessment. The request of Bayer to carry out an assessment is unjustified and will only lead to unnecessary delays.
2) **ED adversity via T-modality has been demonstrated.**

   For both substances the T-modality was considered sufficiently investigated (i.e. no data gaps) and T-mediated adversity (changes in thyroid weight and thyroid histopathology), and T-mediated endocrine activity (changes in TSH and TH,) were observed in studies of different duration and in different species (i.e. rat, mouse and dog).

   For **flufenacet** Bayer claims that there was no adversity observed in developmental neurotoxicity (DNT) in vivo study. This is incorrect as the DNT in vivo study showed adverse effects from the low dose exposure. The fact that the in vitro DNT studies did not detect DNT potential, further supports that the DNT adverse effects observed in vivo were because of the changes in TH and TSH levels.

   For **metribuzin**, Bayer refers to the lack of STOT RE classification by RAC, nevertheless this doesn't mean that thyroid effects are not considered adverse for endocrine disruption. Not only thyroid adversity was observed in different studies but a comparative thyroid assay (CTA) study confirmed the concern that metribuzin perturbs the hypothalamic–pituitary–thyroid (HPT) axis with changes in THs and TSH. The perturbation of HPT axis was observed across the metribuzin data set, which sufficiently indicates the substance's endocrine disrupting properties.

3) **Endocrine disruption assessment is based on expert judgement**

   It's important to note that the classification of these substances has been extensively discussed in the EFSA expert group, and the 2018 EFSA/ECHA guidance document has been followed in detail. The applicants had already raised their concerns about the thyroid adverse effects being non relevant for humans or non-adverse, and these concerns were considered by EFSA WG before reaching its conclusion.

In this regard, we appreciate that ECHA doesn't spend additional resources to re-examine the same comments twice, as it is counterproductive and impedes the objective of this procedure to avoid duplication of assessment, with the overall aim to correctly identify hazardous chemicals.