

To:

Dr Nikolaus Kriz
Executive Director
European Food Safety Authority (EFSA)
Via Carlo Magno, 1A, 43126 Parma, Italy

Brussels, 13/05/2026

Subject: Key lessons from recent EU Court rulings on Pesticide Regulation

Dear Mr. Kriz,

On behalf of PAN Europe, I am writing to bring to EFSA's attention key lessons arising from three recent European Court rulings on pesticides, in two cases brought before the Court by PAN Europe against the European Commission and one national case against the State of Belgium, where questions for preliminary rulings were sent to the EU Court. These judgments provide legal guidance on the implementation of Regulation (EC) 1107/2009 including the obligations incumbent upon EFSA within this legal framework. **We trust that these rulings will be fully taken into account in future EFSA publications linked to pesticide risk assessment.**

- **Cypermethrin (C-316/24 P)**

We first want to draw the Commission's attention to [judgment](#) C-316/24 P of 18 December 2025, in the matter between PAN Europe and the Commission. The case arose following the Commission's rejection of our internal review request concerning the Implementing Regulation (EU) 2021/2049 renewing the approval of the active substance cypermethrin as a candidate for substitution, despite EFSA having identified critical areas of concern. Our action for annulment was initially dismissed by the General Court. We subsequently appealed that judgment to the Court of Justice. In its judgment, the Court of Justice of the European Union set aside the ruling of the General Court and annulled the Commission's decision. The Court ruled that the **European Commission acted unlawfully when it re-approved cypermethrin in 2021**, finding that the decision was not based on a solid and complete risk assessment and relied on unrealistic risk mitigation measures that had never been validated by EFSA.

While many of the Court conclusions concern the Commission (for instance its obligation to ensure that risk mitigation measures included in approval regulations are scientifically validated), several of the Court's findings are also highly relevant to EFSA's work and its obligations.

Indeed, both the General Court and the Court of Justice **reaffirmed a key principle of the the *Blaise judgment (C-616/17)***: approval or renewal of approval of a substance is conditional upon demonstrating that at least one representative use of the product is safe under realistic conditions, in line with Article 4(1)-(3) of Regulation (EC) 1107/2009. Article (3)(b) requires that the products must not have any harmful effects, whether immediate or delayed, on human health. This means that products must not exhibit carcinogenic properties or long-term toxicity. Applying this to cypermethrin, the Court clarified that it is not enough, for the European Commission, to presume that long-term toxicity or cumulative and synergistic effects of the representative use have been adequately assessed by Member States, when authorising cypermethrin-based products. Furthermore, and directly relevant to EFSA's work **it must be positively demonstrated, in the frame of the EU risk assessment, that a long-term toxicity assessment of the representative formulation was actually carried out.** We would like to draw your attention to the systematic absence of a long-term toxicity assessment of the representative formulation(s) in pesticide risk assessment, including in the peer reviews by EFSA. This absence stems from the absence of data requirements, both on individual components such as co-formulants, and on the formulation itself. **Where such an assessment cannot be carried out, based on the data received in the dossier, this should be identified as a critical area of concern (CAoC) by EFSA, according to its definition¹.**

- **Coformulants (T-1148/23)**

This second case arose from the Commission rejection of our internal review request of Implementing Regulation (EU) 2023/574 setting out detailed rules for the identification of unacceptable co-formulants. While the General Court [rejected](#) PAN Europe's annulment request on 22 October 2025, it emphasised the obligations incumbent upon Member States with respect to the assessment of co-formulants and pesticide products under Regulation (EC) 1107/2009. This is also relevant to EFSA's work in the context of its peer-review of the risk assessment of representative formulation(s) of active substances.

In particular, the Court recalled that, pursuant to Articles 11(3), 12(3) and 37(1) of that Regulation, when carrying out the risk assessment of a pesticide formulation, Member States are under the obligation to request additional data where the information submitted by applicants in support of an authorisation is insufficient. **Crucially, where an applicant fails to supply all required information, in particular that necessary for the evaluation of co-formulants, the application must be declared inadmissible and rejected.** This requirement also serves as an incentive for applicants to submit complete dossiers from the outset (§100, 111, 119).

¹ "An issue is listed as a critical area of concern if (...) this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health (...).

Regarding co-formulants present in the formulation(s) for representative use to be risk assessment in the frame of active substances' approvals under article 4(5) of Regulation (EC) 1107/2009, and consecutive to the judgement, to be read in conjunction with the Blaise ruling (in particular §74), it is clear that **EFSA is under the obligation to provide a risk assessment of each co-formulant, individually**. In case of absence of such a risk assessment, this should be identified as a critical area of concern by EFSA.

The Cypermethrin and the Co-formulants judgements, in addition to the Blaise ruling, have provided clear clarifications on the risk assessment of co-formulants and representative formulations. In order to provide fit for purpose risk assessment conclusions, EFSA must ensure that its scientific peer reviews and statements are fully aligned with the law and the relevant case law. We are therefore very concerned to observe that publications from 2026, such as EFSA's peer review on Ziram², still do not apply the lessons from these judgements. In this peer review, EFSA indicated that it had not received sufficient information to carry out a proper risk assessment for all co-formulants. This should lead, by law, to a CAoC. In addition, EFSA does not mention anywhere that it was not able to carry out a proper risk assessment on the long term toxicity of the representative formulation which should, according to its definition, also be a CAoC.

We respectfully request that EFSA corrects its Scientific peer reviews that were published after the co-formulants and cypermethrin judgements to ensure they comply with the law.

- **Emergency authorisation (C-162/21)**

Lastly, we would like to recall the preliminary ruling C-162/21 of 19 January 2023 in which the Court of Justice of the European Union made clear that Article 53 of Regulation (EC) 1107/2009 cannot be interpreted as allowing the authorisation of plant protection products or uses that have already been prohibited on grounds of human health or environmental protection (§50). We are therefore very concerned that recently published EFSA protocols for the assessment of emergency authorisations under Article 53 do not reflect the findings of Case C-162/21³. These protocols provide Member States with the option to grant derogations in situations where: *“the active substance was evaluated and the criteria in Annex II are not satisfied, or there are serious concerns regarding the safety of the active substance for human health, the environment, or non-target organisms.”* Such an option is clearly incompatible with the Court's ruling. Accordingly, **the protocols concerning insecticides, acaricides, fungicides and bactericides must be revised to ensure full alignment with Article 53** of Regulation (EC) No 1107/2009 as interpreted by the Court. Moreover, EFSA should ensure that the forthcoming protocol on herbicides is fully compliant with Case C-162/21.

² <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9869>

³ For instance <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2026.EN-9905>, p. 31

This matter is particularly urgent given that EFSA is planning training sessions on these protocols as of the end of May⁴. It is therefore essential that this inconsistency be corrected prior to their dissemination and implementation, in order to avoid consolidating an interpretation that is not in line with the EU case law.

In this regard, may I ask you to confirm that these protocols will be corrected and brought to alignment with the law before the training sessions take place?

In summary, PAN Europe respectfully asks EFSA to:

- Carry out an individual risk assessment of each co-formulants present in the representative formulation(s). Where such an assessment cannot be carried out, in particular regarding their long-term toxicity to humans, this should be identified by EFSA as a CAoC, precluding the approval or renewal of the concerned active substance.
- Assess the long-term toxicity of the representative formulation(s). Where such an assessment cannot be carried out, EFSA should identify this as a CAoC, precluding approval or renewal of the active substance in question.
- Ensure that all protocols for the evaluation of emergency authorisations of pesticides under Article 53 are aligned with ruling C-162/21.

I thank you in advance for your reply and I remain available to discuss these issues further.

Yours sincerely,

Angeliki Lyssimachou

Head of Science and Policy

PAN Europe

Contact details:

Dr Angeliki Lysimachou, Head of Science and Policy, angeliki@pan-europe.info, +32 2 318 62 55

Salomé Roynel, Policy Officer, salome@pan-europe.info, +32 451 02 31 33

PAN Europe, Rue de la Pacification 67, 1000, Brussels, Belgium

[Who we are | PAN Europe](#)

⁴<https://www.efsa.europa.eu/en/events/training-evaluation-emergency-authorisations-pesticides-using-efsa-protocol-insecticides-and>