Pesticide Action Network Europe

To:
Ms Claire Bury
Deputy Director-General responsible for Food sustainability
Rue Breydel 4, 1040 Brussels, Belgium

Brussels, 13/05/2026

Subject: Key lessons from recent EU Court rulings on Pesticide Regulation - Cypermethrin endocrine disruptor

Dear Ms. Bury,

On behalf of PAN Europe, I am writing to bring to the Commission's attention key lessons arising from three recent European Court rulings on pesticides, in cases brought before the Court by PAN Europe against the Commission. These judgments provide important legal guidance on the implementation of Regulation (EC) 1107/2009, and clarify the obligations incumbent upon the Commission under this legal framework. **We trust that these rulings will be fully taken into account in future regulatory practice.**

- **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 European 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. 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 the European Food Safety Authority (EFSA).

A key takeaway from the General Court judgment is that **when EFSA identifies critical areas of concern, the Commission may only depart from those conclusions, and from the precautionary principle, if it can demonstrate, on the basis of solid evidence, that risk mitigation measures ensure compliance with Article 4(1)-(3)** of Regulation (EC) 1107/2009 (§102). This requires the Commission to act on verifiable scientific evidence In the first ruling, the General Court considered this to be the case for cypermethrin. However, on appeal, the Court of Justice disagreed and found that the General Court had failed to verify two issues. First, whether the representativeness of the batches had been properly established. Second, whether the proposed risk mitigation measures to reduce exposure for off-field non-target arthropods (NTAs) were realistic and therefore practically effective. We would like to draw your attention to the fact that the representativeness of batches is a recurring issue highlighted by EFSA in its peer review conclusions. Similarly, non-validated risk mitigation measures have also been relied upon in the re-approval of other pesticides, such as abamectin, captan, and quinoline-8-ol. The current proposal to renew mecoprop-P, discussed in SCoPAFF, is also based on mitigation measures that do not adequately address the risk identified for children, in particular the exceedance of the Acceptable Operator Exposure Level (AOEL).

Moreover, 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 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 products must not exhibit carcinogenic properties or long-term toxicity. Applying this to cypermethrin, the Court clarified that it is not enough to presume that long-term toxicity or cumulative and synergistic effects of the representative use have been adequately assessed. **It must be positively demonstrated that a long-term toxicity assessment of the representative formulation was actually carried out.** The Commission failed to make that demonstration, and the General Court failed to verify it (§283, 285, 289, 290, 301, 302). We would like to draw your attention to the systematic absence of a long-term toxicity assessment of the representative formulation in pesticide risk assessment. This absence stems from the absence of data requirements, both on individual components such as co-formulants, and on the formulation itself (mixture toxicity).

Last, Article 6(f) of Regulation (EC) 1107/2009 about **confirmatory information cannot consist of information which should have already been submitted in the renewal dossier**. In other words, it should not apply to situations where the application dossier is incomplete, in line with point 2.2 of Annex II of Regulation 1107/2009 (§215, 237).

In accordance with Article 266 TFEU, the Commission must take all necessary measures to comply with this judgment and to give full effect to the Court's ruling within a reasonable time.

- **Dimoxystrobin (T-412/22)**

This case challenged the Commission's rejection of our internal review request concerning the Implementing Regulation (EU) 2021/2068 extending the approval period of a series of active substances, including the approval of dimoxystrobin for the seventh time. Although dimoxystrobin was ultimately not renewed under Implementing Regulation (EU) 2023/1436, the General Court considered it necessary to rule on the legality of the contested extension of approval to *"prevent alleged unlawfulness recurring in the future"* (§26). In its judgment T-412/22 from 19 November 2025, the Court provided important clarifications on the Commission's use of approval extensions under Article 17 of Regulation (EC) 1107/2009.

In particular, the Court emphasised that **such extensions are, by nature, temporary and exceptional measures**, intended solely to allow the completion of an ongoing renewal procedure. They cannot be applied automatically, repeatedly or systematically. The Commission is required, in each individual case, to carry out a concrete assessment of the specific circumstances and to determine a period that is strictly limited to what is necessary to finalise the scientific evaluation (§79,85). The Court further clarified that repeated or overly long extensions risk undermining the effectiveness of the renewal system established by the Regulation. **It cannot be accepted that an extension of approval to allow an active substance to stay on the market for a duration significantly exceeding the original approval period deprives the regulatory framework of its practical effect** (§80)**.** Finally, the judgment recalls that, when exercising its powers under Regulation (EC) 1107/2009, the **Commission must fully respect the precautionary principle** and ensure that the objective of protecting human and animal health and the environment takes precedence over considerations related to agricultural production (§78).

Since the publication of the judgment, the Commission has put forward several draft Implementing Regulations extending the approval period of a large number of active substances. These include candidates for substitution, PFAS, and even substances for which EFSA has identified as an endocrine disrupting substance meeting at least one of the "cut-off" criteria of the Regulation (e.g., cyprodinil, fludioxonil and phenmedipham[1]). The Commission has sought to justify these extensions on a case-by-case basis. However, its approach continues to reflect a pattern of systematic prolongation. This practice cannot be reconciled with the exceptional and temporary nature of extensions emphasised by the General Court. It is particularly unacceptable because it also concerns substances of concern whose approval periods have already been more than doubled as a result of repeated extensions (e.g., deltamethrin and chlorotoluron)[2].

Finally, we would also like to express our dismay regarding the approach taken by the agents of the Commission during the hearing in this case. We were surprised by certain arguments raised, which appeared at times to align more closely with the position of the pesticide industry than with the defence of the Commission's values or the public interest. In particular, one agent emphasised that it would not be in the interest of industry to submit incomplete dossiers and slow down the

[1] D115113/01 - Comitology Register
[2] D113886/02 - Comitology Register

regulatory process. This statement is contradicted by the reality in a majority of applications. Indeed, facts show that delays in the process, due to incomplete re-application dossiers will in practice prolong the period during which substances remain on the market prior to any restriction or withdrawal. This has been the case for numerous substances that were, in the end, banned because they do not meet the safety criteria. This is not the first time that PAN Europe has observed such behaviour from your agents, arising in the context of a Court hearing[3]. We therefore respectfully request that the Commission ensures that its legal representatives consistently act in full alignment with their mandate and with the public interest at all times.

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

This last 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 clarified the obligations incumbent upon Member States with respect to the assessment of co-formulants and pesticide products under Regulation (EC) 1107/2009.

In particular, the Court recalled that, pursuant to Articles 11(3), 12(3) and 37(1) of that Regulation, Member States are under an obligation to request additional data where the information submitted by applicants in support of an authorisation is insufficient. **Crucially, where an applicant fails to provide 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). The judgment therefore confirms that information relating to co-formulants forms part of the substantive assessment required under Regulation (EC) No 1107/2009. We trust the Commission will clearly communicate this obligation towards Member States.

Regarding the formulation(s) for representative uses to be assessed under Article 4(5) of Regulation (EC) 1107/2009, and in light of the judgment, read in conjunction with the Blaise ruling (in particular §74), it follows that **EFSA is required to carry out an individual risk assessment for each co-formulant.** Any approval granted in the absence of such an assessment would be contrary to Regulation (EC) 1107/2009 and to judgment T-1148/23.

In addition, in PAN Europe 's view, this judgement confirms PAN Europe's longstanding position: a major legislative gap prevents a proper implementation of Regulation (EU) 2023/574. As PAN Europe commented in the public consultation on that regulation[4], and as highlighted to your services in numerous instances, in order to carry out a proper risk assessment of co-formulants, the European Commission should have set data requirements, as it did in Regulation (EU)

[3] See letter sent to Commissioner Kyriakides dated 27/01/2023, on ruling C-162/21

[4]https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13416-Plant-protection-products-pesticides-identification-of-unacceptable-co-formulants/F3358242_en

2024/1487 on safeners and synergists. This judgement thus confirms the obligation of Member States to carry out a thorough risk assessment of co-formulants and requires the 27 Member States to request the necessary data from the industry. As communicated to you in the frame of the preparatory work prior to the adoption of Regulation (EU) 2023/574, the Commission approach risks leading to an uncoordinated approach, as no harmonised data requirement has been set at EU-level, already three years after the publication of the co-formulants regulation. We therefore encourage the Commission to take a similar approach as for safener and synergists, i.e. request for similar data requirements as for active substances, in order to ensure the same level of protection, as requested by Regulation (EC) 1107/2009.

In summary, PAN Europe respectfully asks the Commission to:

- Ensure that risk mitigation measures included in approval regulations are scientifically-proven;
- Ensure that any dossier in which the batches used are not similar to the representative formulation is rejected and the pesticide is not (re-)approved;
- Do not set confirmatory information that consists of information which is considered mandatory in the renewal dossier to assess whether the approval criteria are met;
- Stop (re)-approving pesticide active substance for which no risk assessment of the long-term toxicity has been carried out;
- Stop (re-)approving pesticide active substance for which data on long-term toxicity of co-formulants is not provided by the industry in the application dossier;
- Amend the data requirements under Regulation (EU) 284/2013 to include 1. Mandatory data on long-term toxicity for formulations, similar to that requested for active substances and; 2. Mandatory data requirements for co-formulants similar to those requested for active substances, in order to enable Member States to identify unacceptable co-formulants, in line with Regulation (EU) 2023/574;
- Clarify with Member States that they cannot provide a (re-)authorisation of a plant protection product without a proper risk assessment of all co-formulants;
- Ensure a strict implementation of the legal timeline foreseen under Regulation (EU) 844/2012 and Regulation (EU) 2020/1740 to avoid providing yearly extensions of approvals. Ensure that incomplete applications are systematically rejected by Member States in order to avoid backlog and extra work for competent authorities, a backlog that strongly contributes to the current situation of massive delays in the regulatory process. The Commission should launch infringement procedures against Member States that do not fulfil the deadlines to pressure them to raise administrative fees and hire relevant staff.

Moreover, we trust the Commission will clearly communicate to EFSA its now clarified legal obligation 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, this should be identified as a Critical area of concern by EFSA 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, this should be identified as a Critical area of concern by EFSA precluding the approval or renewal of the concerned active substance.

- **Implementation of the emergency authorisation ruling from 2023 still pending (C-162/21)**

Lastly, we would also like to inquire about the state of play regarding the adaptation of the Commission Guidance Document on emergency authorisations following ruling C-162/21. The document has been indicated as "Under review" on the Commission website for at least two years, yet no visible progress has been communicated. More than three years after the ruling, it is surprising that the Guidance Document has not yet been updated. We would like to respectfully recall that, in point 50 of the ruling, the Court made it clear that Article 53 of Regulation (EC) No 1107/2009 must not be used to authorise pesticides or uses that have been banned for health or environmental reasons. This key clarification should be explicitly reflected in the Guidance Document. In practice, however, a number of Member States continue to grant derogations for uses or substances that are banned at EU level. For example, in 2026, Belgium granted a derogation for uses of cypermethrin that have been banned since 2021. Spain and Greece also granted derogations for the use of abamectin in open fields, despite the fact that its use is legally restricted to closed spaces by regulation (EU) 2023/515. Such derogations appear difficult to reconcile with the requirements set out in ruling C-162/21. In previous years, derogations have also been granted for substances banned, or whose application was rejected because they do not meet the EU health and environmental safety criteria, such as diquat and 1,3-dichloropropene. These examples further highlight the need to swiftly update the Guidance Document. In this context, we would be grateful if you could clarify whether DG SANTE intends to initiate infringement procedures in relation to these practices. We would also appreciate receiving an indicative timeline for the adoption of the revised Guidance Document.

We would further also like to take the opportunity to highlight the fact that the recently published protocols for the evaluation of emergency authorisations of pesticides under Article 53 of Regulation (EC) 1107/2009 do not respect ruling C-162/21[5]. Indeed, in these protocols, the EFSA gives the option to Member States to provide derogations in the following case: "Active substance was evaluated and criteria in Annex II not satisfied or there are serious concerns on the safety of the active substance to humans or the environment or any non-target organisms". This option evidently clashes with the ruling. We respectfully ask you to mandate EFSA to revise its protocols regarding insecticides, acaricides, fungicides and bactericides in accordance with the law and case law. The EFSA should also ensure that the upcoming protocol on herbicides complies with ruling C-162/21. This is the more urgent as EFSA is planning training sessions on its protocols as from end of May[6]. The error should thus be corrected by then.

[5] For instance https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2026.EN-9905, p. 31
[6]https://www.efsa.europa.eu/en/events/training-evaluation-emergency-authorisations-pesticides-using-efsa-protocol-insecticides-and

In the current context of political instability, it is particularly important that public institutions lead by example and demonstrate the highest standards of integrity in order to strengthen public trust. PAN Europe expects that the Commission will fully integrate the legal lessons arising from these rulings into its decision-making practices and ensure strict compliance with Regulation (EC) No 1107/2009. These rulings represent an important step forward in the protection of citizens' health and the environment. In this regard, we would be grateful if you could inform us of the measures that have been put in place within the European Commission to implement the lessons derived from these rulings.

We remain available to discuss these issues further.

Yours sincerely,

Martin Dermine

Executive Director

PAN Europe

Contact details:
Dr Martin Dermine, Executive Directive, martin@pan-europe.info
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