

LET/25/CF/39094  
23 September 2025



## CLE Letter to SCoPAFF meeting 1-3 Octobre 2025

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### Topics

#### Topics on the Agenda

- ED and thyroid function
- Guidance documents
- TFA
- PPPs - Biostimulants clarification
- Impurities in PPPs

#### Outstanding topics

- NTTO Guidance

Dear SCoPAFF members,

CropLife Europe is pleased to offer feedback on several matters on the agenda or of broader relevance.

### Topics on the Agenda

#### **A.03.3 : Report on ED criteria and**

#### **A.12.6 : Implementation ED criteria / T modality and human relevance**

These topics raise our attention, and we remain available to better understand the discussion and to follow up with a proper scientific input.

## **A.07 Guidance Documents, in particular:**

### **2. Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment; 3. Technical guidance on the assessment of negligible exposure to an active substance, safener or synergist in a plant protection product under realistic conditions of use (pro memoria)**

CropLife Europe considers that for a sound feedback mechanism and input into the process, a thorough and transparent understanding of the timing is relevant. We'd like to understand when the period for comments will start.

#### **A.10.1 Trifluoroacetic acid (TFA)**

CropLife Europe reiterates that applicants must be granted sufficient time to generate data in support of a substance-by-substance evaluation. We regret, however, that this principle has not been applied consistently, with proposals for non-renewal being made in the absence of evidence-based indicators on TFA formation.

To ensure legal certainty and regulatory soundness, applicants should have the time to generate data according to agreed metrics and protocols, and these should be communicated clearly and transparently if departing from the standard methods used as stipulated in an agreed set of data requirements and guidance documents.

## **A.12**

### **1. Scope of Regulation (EC) No 1107/2009:**

#### **a) Scope document rev.78**

In the context of potential consultations to amend Regulation (EU) 2019/1009 as to authorize fertilising product blends containing phosphonates/phosphites to be marketed as plant biostimulants, CropLife Europe would like to reiterate its opposition to this proposal. All active substances intended to protect plants should continue to require an authorisation according to the procedure circumscribed by Regulation (EC) No 1107/2009 and be unambiguously marketed as plant protection products to avoid misuse. Phosphonates and phosphites are chemically identical, and were clearly demonstrated to exhibit fungicidal properties.

It is in the interest of protecting human health that their use in biostimulants use should not be permitted, to avoid risk to operators and workers, who unknowingly might use products which they consider as fertilisers while they actually contain active substances. Moreover, inclusion of phosphonates and phosphites in fertilising products under Regulation (EU) 2019/1009 gives rise to a real risk of exceeding the MRLs established by Regulation (EC) 396/2005 beyond safety levels potentially affecting consumers. The use of phosphonates/ phosphites as biostimulants could generate an increased risk for leaching into surface waters and for affecting biodiversity.

Any additional labelling warnings cannot avert the real risk that use of phosphonate-containing biostimulants poses and would only shift the responsibility to farmers.

#### **A.12.4 . “New” impurities found in plant protection products**

CropLife Europe would like to better understand the terms of discussion and remains available to provide support in this area.

## Outstanding topics

### Upcoming EFSA Guidance on Indirect Effects on biodiversity via trophic interactions and Review of the Terrestrial Ecotoxicology Guidance Document

CropLife Europe has thoroughly reviewed EFSA's recently published Strategy to develop Specific Protection Goals (SPGs) for non-target arthropods (NTAs), non-target terrestrial plants (NTTPs) and soil organisms in line with the mandates it received from the European Commission in June 2024 to review the Terrestrial Ecotoxicology Guidance document and to develop a new Guidance on indirect effects on biodiversity via trophic interactions.

CropLife Europe considers that while important, the proposed SPG Strategy risks making the registration of plant protection products (PPPs) disproportionately difficult. The approach is unduly conservative and leaves little scope for risk managers to balance manageable risks against clear agricultural benefits. The introduction of highly conservative SPGs and indirect effects would add unnecessary complexity to an already demanding regulatory framework, contradicting the Commission's stated ambition on simplification. Ultimately, this could further reduce farmer's access to tools they need to protect their crops against pests, weeds and diseases. CropLife Europe believes the proposed SPG Strategy can and should be improved to ensure proportionate risk management, as mandated by the European Commission, while contributing to the EU's policy goals on food security, sustainability and competitiveness, namely by considering the overall agricultural context, integrated crop management (ICM) practices, the role of recovery in agricultural ecosystems, and the relative risks of alternative pest control methods. Please find CropLife Europe's detailed analysis in the attached position paper (Annex I).

We remain available in case of any questions.

Yours sincerely,

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Director of Regulatory Affairs



cc.

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Eric Liegeois  
Manuela Tiramani

*This letter will be published on the CropLife Europe website and will be available at:*  
<https://croplifeeurope.eu/resources-library/>