

LET/26/KH/39698
19 June 2026



Almut Bitterhof
European Commission
DG Sante - Unit E.4 - Pesticides and Biocides
1049 Brussels
almut.bitterhof@ec.europa.eu

Kevin Heylen
Senior Regulatory Affairs Manager
+32 (0)2 663 15 56
kevin.heylen@croplifeeurope.eu

CropLife Europe input for SCOPAFF meeting 29-30 June 2026

- **Request to shift Latvia, Lithuania and Estonia to the Central Zone (annex 1 amendment): second discussion**
- **Omnibus Simplification Package (update on co-legislative works)**
- **FOCUS surface water scenarios – temporal percentile**
- **Trifluoroacetic acid (TFA) - Update on Working Group concerning the second EFSA mandate (List – Methods – Fate) (update)**
- **Implementation ED criteria / T modality and human relevance (update)**
- **Co-formulants and assessment of formulations**
- **Court cases, requests for internal review, Ombudsman cases**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 29-30 June 2026, CropLife Europe would like to provide input on several issues:

A.03(4) - Request to shift Latvia, Lithuania and Estonia to the Central Zone (annex 1 amendment): second discussion

CropLife Europe acknowledges the discussions within its working group regarding potential changes to the current zonal configuration.

While these proposals aim to address challenges in access to crop protection solutions, CropLife Europe maintains that **modifying the existing zonal system is unlikely to provide an effective solution**, as the **expected benefits remain uncertain and insufficiently demonstrated** to justify a structural change of this magnitude.

Such changes would, in any case, **entail significant short- to medium-term disruption**, including updates to guidance, reallocation of zRMS responsibilities, and the transition of ongoing evaluations. This would increase the overall workload for authorities and applicants and risk delaying both ongoing and new product authorisations.

In this context, **a comprehensive impact assessment and a cost/benefit evaluation with the involvement of all stakeholders should be carried out before any decision is taken**, in order to properly evaluate the scale of the transition efforts against the expected benefits.

In the meantime, CropLife Europe reiterates that **existing mechanisms should be fully leveraged**, in particular interzonal mutual recognition and further simplification of national requirements, to improve the availability of solutions for farmers.

A.03(5) - Omnibus Simplification Package (update on co-legislative works)

CropLife Europe strongly reiterates its concerns over the Commission Food & Feed Safety Omnibus Proposal to introduce an EU-wide territorial scope of **data protection**. Due to differing authorisation timelines across Member States, in those countries authorising products at a later stage, companies

would face drastically reduced or no data protection. **CropLife Europe is concerned that when data protection is weakened, the incentive to invest in generating new safety data diminishes.** Over time, companies will become more selective in where they invest, especially in areas with lower or less certain returns. This will likely impact renewals, specialty crops, minor uses and label extension. Ultimately, EU farmers would lose access to the innovative crop protection solutions they need, weakening European agriculture's productivity and competitiveness. In addition, companies may be less inclined to rely on provisional authorisations for biocontrol or low-risk substances if the EU-wide data protection period begins on the date the provisional authorisation is granted, thus delaying the availability of fast-track innovative solutions for farmers. Given these significant unintended consequences, CropLife Europe would urge the current data protection system to be maintained and proposes more targeted and proportionate measures to achieve the Commission's objectives: (i) introduction of a sunset clause to increase availability of solutions across the EU, and (ii) introduction of a common EU database of protected tests and study reports to increase transparency.

Additionally, **maintaining the current risk-based MRL framework is critical** to protect consumer safety, provide legal certainty for farmers and companies, support compliance with WTO rules, and safeguard the competitiveness of the EU agri-food value chain and stable international trade. CropLife Europe therefore does not support shifting MRL-setting under Regulation (EC) No 396/2005 away from a risk-based approach towards a hazard-based system. Any proposal to fundamentally change the MRL framework should be preceded by a comprehensive impact assessment, considering different options, relevant scientific evidence and alternative risk management measures, and fully assessing impacts on competitiveness, trade, food security, prices, international standards and supply chains.

The Food & Feed Safety Omnibus Proposal is a timely opportunity to simplify Regulation (EC) No 1107/2009 by addressing procedural inefficiencies that have accumulated over time and are now limiting farmers' access to safe and efficient crop protection solutions. CropLife Europe reiterates that moving towards **targeted data call-ins**, rather than systematic full renewals dossiers, is a constructive shift towards a more agile, risk-responsive system. **Unlimited approvals** for active substances would further support proportionality and reduce administrative workload, while maintaining clear safeguards for regulatory intervention when needed, enabling authorities to initiate reassessments on defined scientific grounds and amend or withdraw approvals through predictable processes.

A.07(5) - FOCUS surface water scenarios – temporal percentile

CropLife Europe would like to reiterate our recommendation that the conclusion regarding the temporal percentile of the protection goal should consider scenario vulnerability and protectivity. **We recommend an overall combined 90th percentile protection goal on a scenario-by-scenario basis, in line with the Ground Water Risk Assessment.** This is proposed in recognition that a single temporal percentile cannot deliver consistent protection across scenarios spanning the 38th to 99th spatial percentile. EFSA's own guidance consistently recognizes that selection depends on the interaction of spatial and temporal percentiles, and that the final decision must also consider socioeconomic impacts.

CropLife Europe has provided the Commission further information regarding the indicative impact assessment provided in our letter of 2 March 2026 "*CropLife Europe input for SCoPAFF meeting 10-11 March 2026*" and would welcome engagement on appropriate criteria for inclusion in an expanded impact assessment (range of crops, e fate and psys-chem properties, etc.).

For awareness, in a FOCUS VC Stage 2 Testing meeting with DG SANTE and EFSA on 8 May, it was confirmed that further evaluation efforts are needed regarding the testing of the new Software Framework.

Given the above-mentioned on-going evaluations and further steps that need to be taken to complete the Stage 2 testing, we would like to reiterate our position that **Member States be given the opportunity to evaluate the new Software Framework for themselves prior to any decision on the temporal percentile.** It is our understanding that EFSA is willing to share the current test software with Member States upon request.

CropLife Europe is currently engaging in further discussions with Member States to discuss in greater depth the testing of the new Software Framework.

As further background, we refer to the attached CropLife Europe poster presented at SETAC Europe Conference in Maastricht in May (Annex 1). We would also like to refer to the attached presentation of

Stage 2 testing results presented by Exponent (Stage 2 testing contractor) at the SETAC Europe Conference in Maastricht that offers a summary of key changes associated with the framework in terms of PECsw response and processing demands (Annex 2).

A.10(1) - Trifluoroacetic acid (TFA) - Update on Working Group concerning the second EFSA mandate (List – Methods – Fate) (update)

CropLife Europe recognizes the concerns regarding trifluoroacetic acid (TFA) in the EU and is supportive of the second joint EFSA / ECHA mandate to consider the fate and behavior of TFA in soil and water. We are keen to work constructively with relevant stakeholders to generate data that will reduce the current scientific uncertainties surrounding the potential for TFA formation and to provide a scientifically robust framework to support regulatory decision making.

CropLife Europe experts consider that Regulation (EC) No 1107/2009 and the associated data requirements provide appropriate tools to address TFA formation. However, we acknowledge limitations in standard data-generation approaches that contribute to existing uncertainties around TFA formation from C-CF₃ group containing active substances, even though the overall data requirements of EU regulation 1107/2009 are fully addressed. Our experts have extensively investigated this issue and, while TFA formation from substances containing a C-CF₃ moiety is one recognized degradation pathway, it is not the only degradation mechanism associated with this chemical functionality.

Given their role in designing and executing regulatory studies, CropLife Europe experts are well placed to provide insight into improved data-generation protocols that could enhance clarity on TFA formation. These insights include:

- Expertise in the synthesis of appropriate radiolabeled test materials to enable robust elucidation of degradation pathways;
- Identification of potential modifications to existing laboratory study designs, informed by OECD test guidelines;
- Generation of higher-tier data, such as field dissipation studies, to quantify TFA formation under realistic conditions; and
- Consideration of the timeframes required to implement and conduct robust, regulatory-compliant studies.

CropLife Europe therefore proposes the development of a standardized, tiered approach to a TFA-focused data generation for C-CF₃ group containing substances, providing greater predictability for both industry and regulatory authorities whilst ensuring a robust outcome.

We have developed a decision tree that could be useful in informing any guidance arising from the second mandate and would welcome the opportunity to share this with the EFSA working group, as well as contribute to its further development to ensure it supports scientifically robust regulatory decision-making.

CropLife Europe strongly believes that a careful and proportionate approach is required to meet the requirements of Regulation (EC) No 1107/2009 while ensuring that farmers continue to have access to effective plant-protection tools. To this end, our experts remain available to support the work under the second mandate and are keen to share their experience with relevant stakeholders to help develop an appropriate framework for scientifically informed decision-making, supported by proportionate data generation and risk assessment.

A.12 (4) - Implementation ED criteria / T modality and human relevance (update)

As previously outlined, CropLife Europe supports establishing clear scientific criteria to examine and review the validity of emerging methods and assays, including thyroid in-vitro models and modelling that may help address the current uncertainty on T-modality ED assessments. This would ultimately enable regulatory decision making with little remaining uncertainties.

In that sense, CropLife Europe requests the European Commission and the Member States to consider providing EFSA and/or ECHA with a mandate to adequately address the current T-modality gap.

Once the work on the T-modality is completed, regulatory decisions can be made with more consistency and confidence in the process, and reach appropriate conclusions using the tools needed for a sound assessment.

A.13 - Co-formulants and assessment of formulations

With reference to the Commission presentation at the March CropLife Europe conference and the 'Follow up workshop on co-formulants' of Commission, Member States and EU agencies on 5 June 2026, CLE would like to reemphasize the need for a functional comprehensive assessment framework and **asks Commission to ensure workability across the relevant regulations**. Clarity on data relevance and availability, as well as both opportunities and pitfalls of moving towards and working with a centralized non-living list, would need to be carefully considered. The need for detailed context and relevance in regulatory decisions will be of utmost importance to focus on compounds with highest relevance for active substance approvals and product authorizations in Europe.

A.16 - Court cases, requests for internal review, Ombudsman cases

Following the Ombudsman complaint lodged by Foodwatch regarding the Food and Feed Safety Omnibus proposal, CLE wishes to share its views. CLE understands that the complaint raises concerns regarding the process followed by the Commission in preparing the proposal and calls for the withdrawal of the package and suspension of the ongoing legislative discussions.

In this context, CLE reiterates its support for the Commission's simplification objectives, particularly those aimed at reducing unnecessary administrative burdens, avoiding duplicative procedures and allowing national authorities to focus resources where they are most needed.

While stakeholders are entitled to raise concerns regarding the preparation of legislative proposals, CLE believes it is equally important that discussions continue on how to improve the functioning of the current system. The operational challenges faced by Member States, applicants and farmers are real and require attention.

For this reason, CLE considers that the ongoing debate should remain focused on delivering meaningful and targeted simplification while maintaining the high standards that support the EU regulatory framework.

Yours sincerely



Kevin Heylen
Senior Manager Regulatory Affairs

cc. Eric Liégeois
Mark Williams
Manuela Tiramani

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

Annex 1 - CropLife Europe poster SETAC Europe Conference - Spatial Representativeness and Temporal Variability in the FOCUS Surface Water Framework: Implications for Future Endpoint Selection (separate document)

Annex 2 – Exponent presentation of Stage 2 testing results (separate document)