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CropLife Europe input for SCOPAFF meeting 05-06 May 2026

- **Request to shifting Latvia, Lithuania and Estonia to the Central Zone (annex 1 amendment): first discussion**
- **Omnibus Simplification Package (update on co-legislative works)**
- **Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment (update)**
- **FOCUS surface water scenarios – temporal percentile**
- **Implementation ED criteria / T modality and human relevance (update)**

Dear SCOPAFF members,

Ahead of the SCOPAFF phytopharmaceuticals-legislation meeting on 05-06 May 2026, CropLife Europe would like to provide input on several issues:

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

CropLife Europe supports administrative efforts to provide farmers gaining timely access to the solutions they need. We encourage member states to address underlying barriers relating to dossier submissions, national requirements, assessment capacity, delays and/or difficulties in mutual recognition and to seek for constructive solutions together with the EU commission based on impact assessments (e.g. redraw of existing zones, voluntary Mutual Recognitions between different zones).

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

Under the Food and Feed Safety Omnibus Package, the Commission proposes to introduce an EU-wide territorial scope of **data protection**, while maintaining the existing protection periods. However, because authorisation timelines differ across Member States, countries authorising products later face drastically reduced or no data protection.

CropLife Europe is concerned that when data protection is shortened or lost, the incentive to invest in generating new safety data diminishes. Over time, this could lead some undesired regulatory consequences, like withdrawal of existing products from the market, or reluctance to apply for minor use extensions. Consequently, 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 at the date of the provisional authorisation is granted. This reduction in effective data protection could discourage companies from applying for provisional authorisations and, in turn, delay the availability of fast-track innovative solutions for farmers.

Given these significant unintended consequences, CropLife Europe would prefer the current system to be maintained, and if not, that the proposal should include appropriate mitigating measures to preserve effective protection where national timelines differ.

Overall, the Food & Feed Safety Omnibus provides a concrete 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. We would like to remind SCoPAFF representatives that the proposal includes clear safeguards for regulatory intervention when needed: authorities can initiate reassessments on defined scientific grounds and amend or withdraw approvals through predictable processes.

A.07(2) - Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009 – draft amendment (update)

Recently several EFSA publications of detailed protocols for the evaluation of emergency authorisations submitted under Article 53 of Regulation (EC) No 1107/2009 have been made available, including for commenting. The stronger emphasis on Integrated Pest Management (IPM) and on the agronomic benefits of certain solutions in these protocols is welcome, as this more holistic approach may justify broader consideration of products that contribute positively to crop management beyond their direct pest control efficacy. On the other hand the protocols are rather complex and seem to overlook the practical challenges faced by manufacturers, particularly regarding production and supply timelines.

In that sense, CropLife Europe recognizes the discussion among MS authorities on the amendment of the overarching Guidance Document SANCO/10087/2013 for emergency authorisations to take these protocols into account, and is looking forward to the latest draft and public consultation of this guidance document.

Although we understand and share the concern that emergency use is a regulatory measure based on derogation, a workable regulatory framework is necessary and should consider a broad spectrum of available solutions, as farmers have been left with a depletion of available crop protection alternatives.

An additional consideration when discussing amending Guidance Document SANCO/10087/2013 could be to grant emergency authorisations earlier in the season to ensure that sufficient quantities of solutions can be made available to farmers in time.

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

CropLife Europe is engaging with the Commission to provide further information regarding the indicative impact assessment provided in our letter of 2nd of March 2026 *"CropLife Europe input for SCOPAFF meeting 10-11 March 2026"*. We are continuing to work on an expanded impact assessment and would welcome engagement on appropriate criteria for inclusion in this work (indication, crop use, substance properties, etc.).

The FOCUS Version Control Stage 2 testing report was provided to EFSA at the end of March and contains a detailed overview of expected changes in predicted concentrations across a range of chemistry types, crop types, and surface water scenarios. If not already underway, Member States should be afforded the opportunity to examine this report to enable them to understand expected changes in outputs for the surface water scenarios which are relevant for their national registration process. We would again advocate that Member States are given the opportunity to evaluate the new Software Framework for themselves prior to any decision on the temporal percentile.

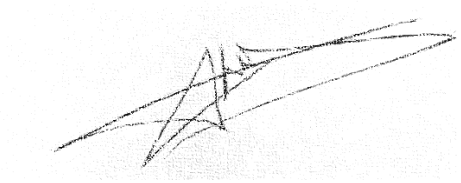
A.12 (4) - Implementation ED criteria / T modality and human relevance (update)

As mentioned previously, CropLife Europe supports to establish clear scientific criteria to examine and review the validity of the 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.

Yours sincerely



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