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CropLife Europe Open Letter to EFSA on Maintaining a Fit-for-purpose Tiered Risk Assessment Framework for Non-target Terrestrial Organisms

Dear colleagues,

CropLife Europe welcomes the considerable efforts invested by EFSA, Member State experts and stakeholders in developing the scientific protocols supporting the revision of the ecotoxicological guidance for non-target terrestrial organisms for pesticide risk assessment. We fully support the objective of ensuring a high level of environmental protection while maintaining a science-based, transparent and workable regulatory system. We also recognise the importance of developing modern risk assessment approaches that reflect advances in ecotoxicological science and contribute to the protection of biodiversity and ecosystem services. At the same time, the publication of the final protocols provides an opportunity to reflect on challenges that deserve attention as the guidance development progresses.

Tier 1 should remain a screening assessment

One fundamental strength of the current regulatory framework is its tiered approach. First tier assessments are designed to be conservative screening tools that efficiently distinguish scenarios where risks are unlikely from those that warrant further refinement. Higher-tier assessments then provide increasing levels of ecological realism and scientific detail where necessary. This principle has enabled authorities, applicants and stakeholders for decades to focus resources where they are most needed. As future guidance develops, it will be important to ensure that the first step in the risk assessment continues to fulfil this screening function.

Complexity should be introduced progressively

The revised protocol identifies a broad range of exposure routes, ecological considerations and testing approaches that may ultimately contribute to the future environmental risk assessment procedures. Many proposals are scientifically valuable and may play an important role in future assessments. However, not every scientifically relevant consideration needs to be addressed within Tier 1. Introducing large numbers of exposure pathways, ecological interactions and sophisticated assessment approaches (for which protocols still need to be developed and validated) at the initial assessment stage risks shifting Tier 1 away from its intended purpose and towards the complexity normally associated with higher-tier assessments. Examples for pesticide entry routes include the simultaneous consideration of multiple dietary and contact exposure for non-target arthropods, additional litter-layer and pore-water entries for soil organisms, as well as surface runoff and root uptake processes for

non-target terrestrial plants. Such specific questions are more appropriately addressed through refinement in higher-tier assessments. Adding increasing complexity at this stage may increase testing requirements, modelling demands and administrative workload without necessarily improving the ecological relevance of derived conclusions.

Increasingly complex Tier 1 requirements could:

- divert resources from the development of scientifically meaningful higher-tier approaches to already complex Tier 1 methods;
- increase assessment burdens for applicants and authorities;
- extend review timelines;
- reduce regulatory predictability; and
- delay access to innovation for farmers.

Environmental protection and regulatory efficiency should not be viewed as competing objectives. An effective tiered risk assessment guidance should deliver both.

The NTTO Tier 1 guidance should remain adaptable

The final protocols represent an important milestone, but they are also the beginning of a longer process. Many key elements of the future framework, particularly higher-tier approaches and their calibration against specific protection goals, remain under development. For this reason, we encourage EFSA to maintain flexibility as the work progresses.

As higher-tier methodologies become available and experience is gained regarding their practical implementation, it may become appropriate to revisit certain aspects of the Tier 1 framework to ensure that the overall system remains proportionate, efficient and scientifically coherent. A willingness to adapt and calibrate the stepwise assessment scheme as knowledge develops would strengthen both scientific robustness and stakeholder confidence.

Moving forward together

A proportionate, tiered approach is particularly important at a time when European agriculture faces increasing challenges related to food security, climate resilience and competitiveness. Regulatory requirements should focus resources on assessments that provide meaningful additional information for decision-making, while avoiding unnecessary complexity at the initial evaluation stage. CropLife Europe remains committed to constructive engagement with EFSA, Member States, farmers, researchers and other stakeholders.

We believe the shared objective should be a risk assessment framework that:

- protects biodiversity and ecosystem services;
- remains scientifically credible and transparent;
- preserves the essential role of tiered assessment;
- focuses complexity where it adds value; and
- enables timely access to innovative solutions that support sustainable agriculture, European Food security and challenges presented by climate change.

We look forward to continuing this dialogue as the guidance development moves forward.

Yours sincerely,

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Director General