POSITION PAPER
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Food and Feed Safety Omnibus Simplification Package

Enable simplification: Protect the farmers' toolbox by reducing administrative burden and duplication and streamlining procedures across the full toolbox (biological and conventional) while fully preserving high safety standards.

Ensure a risk-based approach: Maintain a science-based, proportionate framework grounded in robust risk assessment, targeted reassessment/data call-ins, and workable guidance, with clearer application of key concepts (including alternatives and derogations).

Support competitiveness: Keep Europe attractive for investment by safeguarding innovation incentives and data protection, ensuring trade-consistent, risk-based outcomes, and preventing regulatory-driven market distortions, including through stronger enforcement against illegal and counterfeit products.

Background

The Food and Feed Safety Omnibus is a timely opportunity to remove long-standing bottlenecks in the EU authorisation system, helping farmers access a full range of safe crop protection solutions while maintaining high levels of protection for users, consumers and the environment. With growing pressure on agricultural competitiveness and sustainability, the Omnibus should align the regulatory framework with today's needs and future challenges.

The direction of travel on simplification is positive, including more proportionate approvals as well as renewals and a clearer framework for biopesticides. To truly deliver for farmers and support resilient food systems, simplification and innovation must apply consistently across the entire crop protection toolbox (both biological and conventional) without creating bottlenecks, distortions or trade barriers.

Boost simplification: protect the farmers' toolbox while preserving high safety standards

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.

Moving towards a 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. The proposal also includes safeguards for regulatory intervention when needed: authorities can initiate reassessments on defined scientific grounds and amend or withdraw approvals through predictable processes.

Introducing a future–proof EU definition of biopesticides is a prerequisite for streamlining the authorisation process for these solutions. A "one-zone" approach for biopesticides and low-risk products could substantially reduce duplication and facilitate access across the Single Market. Provisional authorisations are a positive development but they should be available for all crop protection innovations and designed to avoid repeated re-applications that create unnecessary workload for authorities. Faster uptake of biopesticides will also require properly resourced and dedicated parallel regulatory lanes so that accelerating biopesticides does not further delay conventional dossiers.

The Omnibus proposes positive improvements to the functioning of the zonal system, mutual recognition and minor uses extensions which supports more consistency in access across Member States.

Preserve a risk-based approach founded on robust science and proportionality
Any amendments introduced through the Omnibus Package must ensure the risk-based, science-driven foundations of Regulation (EC) No 1107/2009. It should avoid blanket data requirements that are disconnected from real-world exposure scenarios and intended agricultural uses. Instead, proportionality should be strengthened by ensuring that regulatory scrutiny is targeted, justified and grounded in robust scientific evidence.

Proposed changes to renewal procedures under Article 14 will enable more proportionate, data-driven approaches, including data call-in systems focused on identified scientific uncertainties or new risk hypotheses. This could then replace the current practice of full dossier resubmissions that consumes enormous resources without necessarily improving the quality of risk assessments. To simplify and accelerate access to innovative solutions, guidance documents must be developed with practical feasibility checks and applied non-retroactively. This ensures a predictable regulatory environment, allowing farmers to access the essential tools needed for a resilient and sustainable agricultural sector.

A workable risk-based framework also requires clearer implementation of key regulatory concepts. This can be accomplished in accordance with the principle of “no ban without alternatives”, derogations under Article 4(7) and the transparent assessment of the availability of alternatives and agronomic needs. The Omnibus Package has to support a more structured and science-based evaluation of alternatives through thorough consideration of agronomic needs in a dedicated procedural step, ensuring that withdrawals of active substances do not occur in the absence of viable solutions to manage plant health risks. Similarly, clearer criteria and guidance on concepts such as negligible exposure will enable more consistent, proportionate decision-making across Member States.

Ensure competitiveness by safeguarding innovation, trade consistency and data protection
The Omnibus Package’s objective is to ensure that simplification of Regulation (EC) No 1107/2009 strengthens, rather than undermines, the competitiveness of European agriculture and the EU’s innovation ecosystem. Procedural delays, regulatory unpredictability and fragmented implementation across Member States have significantly reduced the attractiveness of the EU market for investment in new crop protection technologies. We are concerned that proposed changes to data protection and data exclusivity (Articles 14, 59 and related provisions) would weaken incentives for innovation and high-quality data generation. In particular, calculating protection from “first authorisation” would materially reduce effective protection in later-authorising Member States and risk competitive distortions.

Competitiveness also depends on maintaining trade-consistent, risk-based regulatory outcomes. Unilateral EU requirements that are disconnected from international standards risk disrupting supply chains without delivering additional safety benefits. Closer alignment between active substance approval procedures under Regulation (EC) No 1107/2009 and related decisions, such as maximum residue levels under Regulation (EC) No 396/2005, should prevent regulatory bottlenecks and support timely market access for authorised products. We are concerned that provisions to set import tolerances on a hazard-based basis would represent a significant departure from established risk-based assessment principles and could create potential inconsistencies with WTO obligations. Such a shift risks tangible repercussions across EU value chains: reduced availability of key inputs and higher costs for European farmers (including for protein feed), risks to supply continuity and upward pressure on food prices for consumers, and broader impacts on EU competitiveness.

Finally, a competitive framework requires effective enforcement against illegal and counterfeit products, which distort markets and undermine confidence in the regulatory system. The Omnibus should strengthen and harmonise enforcement tools so legitimate operators are not disadvantaged by uneven controls, including for products in transit, or by legislative loopholes related to parallel trade (Article 52). The Official Control Regulation (EU) 2017/625 should also provide for effective, dissuasive penalties and include provisions to address online sales, in line with the Digital Services Act (EU) 2022/2065.