

Food and Feed Omnibus: Proposal for Regulatory Data Protection

Predictable, properly enforced regulatory data protection is essential to sustain investment in the high quality scientific studies required to meet the EU's stringent safety standards.

An EU-wide territorial scope, with protection starting from "first authorisation" or first renewal, could materially shorten effective protection in later-authorising Member States. This could undermine predictability for data generators and will weaken incentives to invest in high quality studies, leading to a loss of products.

Any reform should explicitly safeguard meaningful and enforceable data protection across Member States and include mitigation measures to avoid unintended loss of protection and reduced incentives for innovation.

Background

In December 2025, the European Commission presented a Food & Feed Safety Omnibus proposal including amendments affecting regulatory data protection under Regulation (EC) No 1107/2009. Predictable and enforceable data protection matters because it underpins investment in the high-quality studies that regulators rely on to maintain the EU's stringent safety standards. CropLife Europe supports simplification and transparency but any reform needs to preserve meaningful, workable data protection so Europe remains attractive for innovation while maintaining fair competition.

What regulatory data protection is and why it matters

Under the current framework for the authorisation of plant protection products, regulatory data protection is a time-limited safeguard that protects the use of certain studies required by EU law for the authorisation and renewal of plant protection products. It serves two objectives: (1) supporting a robust evidence base that can evolve as scientific guidance develops; (2) enabling companies to recover part of the substantial investment needed to generate safety data, while reducing unnecessary duplication of vertebrate testing. Generating a full safety dataset typically involves hundreds of studies (often 200 - 1,500), over several years and costing millions of euros.

How the system works in practice

Data protection is triggered when new, necessary studies are required for the evaluation of an active substance, or for the new authorisation or re-registration of a formulated product. Once a product is authorised in a Member State, certain studies may benefit from a defined period of protection (for example, 10 years for studies necessary for a new product and 2.5 years for an existing product where they have not already been protected).

Effective data protection in practice depends on a data matching step. This is when competing products are required to rely on the same safety standard, competitors must either generate their own equivalent data or obtain access to the protected studies (for vertebrate studies, this is typically through compensation-based access arrangements). Without this data matching step, protection can become largely theoretical and investment in safety data could never be recovered.

Against the backdrop of a shrinking toolbox (89 active substances lost in the past 6.5 years), maintaining credible incentives to generate high-quality safety data is increasingly important.

Why the proposed EU-wide territorial scope risks eroding effective protection

The proposal would shift from a Member State-by-Member State approach to an EU-wide territorial scope, with the protection period starting from the first authorisation. This risks a significant unintended consequence: Member States finalise authorisations at different speeds and at different points in time.

If protection starts in the first Member State, but other Member States complete their assessments much later, a large part of the protection period may have already elapsed before effective market access is achieved across the EU. This is particularly problematic for renewals and reviews, where much of the current investment in safety data is made and where protection periods can be shorter. The result is a misalignment between the start of protection and real regulatory and market timelines, undermining predictability and weakening incentives to invest in the safety data regulators require. This matters because if effective protection is shortened, the incentive to generate renewal data weakens; at the very moment when renewals account for a growing share of safety investment.

CropLife Europe supports the objective of simplification. However, without addressing this timing misalignment, an EU-wide scope could unintentionally reduce effective protection, distort competition across Member States and weaken the EU's longer-term competitiveness and innovation incentives.

Harmonised, effective implementation is necessary for the proposal to achieve its objectives

To achieve simplification, transparency and improved availability across the EU, an EU-wide approach should be accompanied by a harmonised mechanism that mitigates the unintended effects of starting the clock in one Member State while authorisations conclude later elsewhere. Several options could achieve this, including extending protection periods to ensure protection remains meaningful under an EU-wide approach, particularly for first authorisations and for data generated to support renewals/reviews. Alternatively, where one Member State relies on a protected study during a renewal or review, other operators marketing equivalent products could be required, within a reasonable timeframe, to either rely on the same data (against compensation) or generate equivalent data. This would ensure EU-wide protection better mirrors real regulatory practice and avoids situations where protection expires before comparable regulatory steps occur elsewhere. The concept builds on principles reflected in Article 43 but would apply them in a clearer, transparent and enforceable way.

These adjustments would preserve incentives to generate high-quality data while maintaining timely competition, supporting both innovation and affordability for farmers.