



Agri-Industry Briefing

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EU Proposal to Simplify Pesticide and MRL Legislation – Key Points for the Agri Industry

On 16 December 2025, the European Commission published its Simplification Omnibus Package, proposing extensive amendments to the EU's food and feed safety acquis, including the two most relevant frameworks for the plant protection sector:

- Regulation (EC) No 1107/2009 (approvals, authorizations, data protection)
- Regulation (EC) No 396/2005 (Maximum Residue Levels).

These proposed changes aim to streamline procedures, cut administrative burdens, and increase legal certainty while – according to the Commission – maintaining a high level of protection for human, animal, and environmental health. Importantly, this package is only the Commission's initial proposal; the legislative process has not yet begun, and the final outcome remains entirely open.

Please find below a high-level overview of the key proposals most relevant for the Agri-Industry:

Unlimited Approvals for Most Active Substances

The Commission proposes a fundamental shift: most active substances would receive unlimited approval durations, replacing the current model requiring periodic renewals.

Exceptions would apply to Candidates for substitution, substances approved under Article 4(7) (serious danger derogation), and cases where the risk assessment justifies a time limited approval. The Commission would retain the ability to trigger targeted reassessments when new scientific or technical evidence emerges.

OUR VIEW: This reform is meant to ease regulatory workloads significantly and prioritize resources for new active substances and innovative solutions – objectives with which the industry will concur. However, the essential question will be the effect of the opportunity to trigger targeted reassessment. If the standard is low and used in cases where risk and science do not require it, it can cause unpredictability and uncertainty or

even reduce approval periods significantly. A clear watchout for the coming legislative exchange.

Harmonized EU Wide Data Protection

The Omnibus proposal introduces a single, harmonized EU wide start and end date for data protection of test and study reports. Hence, it abolishes the system of deviating periods in member states. Protection would last 10 years as a general rule and up to 13–15 years in specific cases (e.g., low risk substances, minor use extensions).

OUR VIEW: This eliminates today's fragmented national timelines and reduces the cost and complexity for follow-on applicants – especially relevant for and beneficial for generics. It can, however, have a negative impact on business cases for innovative products. Another watchout!

MRL Reform (Regulation 396/2005)

The proposal would allow Import MRLs under Article 14 to be set at the limit of quantification (LOQ) for certain hazardous substances – such as CMRs, endocrine disruptors, POPs, PBT and vPvB substances – that are not approved in the EU, subject to an impact assessment. In this context, the term “import tolerance” is removed and replaced by a reference to good agricultural practice in third countries, and the Regulation consistently uses the analytical term LOQ instead of LOD to align with international laboratory standards.

OUR VIEW: This follows the repeated practice to extend the MRL-objectives from solely risk-based public-health protection to a hazard-based system and also referring to environmental aspects. A topic with huge political dispute potential. Some will refer to the need to create a level playing field for EU farmers. Others will point to international agreements like the SPS-agreement requiring a solely risk-driven MRL practice as well as regulations like this paternalize non-EU science-based countries.

Other PPP Relevant Simplifications include

- *Accelerated procedures for biocontrol & low risk PPPs:* priority assessment, provisional authorizations before EU approval, one zone authorization, and reduced record keeping obligations.
- *Tacit approval:* authorizations for biocontrol and low risk PPPs are deemed granted if Member States do not decide within 120 days.
- *Drone application:* framework enabling future approval of PPP application by drones, including identification of low-risk drone types and EFSA guidance for drone specific risk assessments.

- *Mutual recognition & minor uses*: simplified procedures, broader acceptance of minor use extensions, and empowerment for harmonized EU wide rules.
- *Essential use derogation*: clarified scope and removal of mandatory phasing out plans.
- *Treated seeds*: prohibition of sowing seeds treated with non-authorized PPPs and clarified rules for all plant reproductive material.
- *EFSA support & scientific clarification*: optional EFSA assistance for rapporteur Member States and clarified interpretation of “current scientific and technical knowledge.”
- *Plant health emergency uses*: priority handling and one zone authorization for PPPs used against regulated pests under the Plant Health Law.
- *Basic substances*: permitted to be placed on the market for plant protection purposes and clarification of coexistence with regular active substance approval.
- *Grace periods*: extended maximum grace periods of up to 36 months for withdrawal of PPPs where no alternatives exist (excluding serious risks).

Next Steps & Outlook

The Commission’s proposal is only the starting point of the ordinary legislative process, not final legislation. Parliament and Council will now examine the text, and core elements may still change substantially as amendments are drafted, new provisions are introduced, and sensitive chapters are reworked. Stakeholder involvement will intensify once rapporteurs are appointed and Council working groups begin their technical review. The proposal will then move through consultations, negotiations, and eventually trilogues, with politically contentious issues - such as unlimited approvals, LOQ based MRL reductions, data protection, and mutual recognition rules – expected to trigger significant debate. No official legislative timeline exists, and any expectations about timing remain purely speculative, as neither institution has issued a schedule.

What This Means for Businesses

Even though the final text remains uncertain, companies should begin:

- Mapping potential impacts of LOQ based MRLs on imports and supply chains,
- Evaluating PPP portfolios in light of unlimited approvals,
- Reviewing data protection strategies,
- Following institutional developments to adjust advocacy positions as amendments appear.

Conclusion

The Simplification Omnibus Package marks a potentially transformative development for EU pesticide and residue legislation. At this stage, however, it is only a proposal, and the final substance will depend on decisions by the European Parliament and the Council. Stakeholders will need to prepare for the political debate and industry will need to anticipate potential portfolio impacts.

For more details please see the EU Commission's [Proposed Legal Text](#) or [Explanatory Memorandum](#).

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