

# Food and Feed Safety Omnibus: Securing the Competitiveness of the Farmers' Toolbox

Make Article 4(7) workable by embedding a structured agronomic and agro-economic assessment: Decisions on derogations should systematically consider real-world feasibility of alternatives (efficacy, scalability, cost/yield, operational constraints, IPM/resistance and uneven availability), so essential uses are not lost where no viable options exist.

Improve flexibility in derogation submissions to reflect real farm realities: Allowing essential-use and/or negligible-exposure elements to be substantiated during approval or renewal enables timely, evidence-based decisions when criticality is clearest and when access is at risk while maintaining high safety standards.

Apply predictable grace periods to avoid disruption: Extended grace periods (up to 12 months for sale and 24 months for use) should apply systematically for non-renewals, except where withdrawal is based on serious human health or environmental concerns; conditioning grace periods on “absence of alternatives” risks duplicative, derogation-like assessments and added complexity.

## Background

The European Commission's Food and Feed Safety Omnibus proposal introduces important revisions to Article 4(7) of Regulation (EC) No 1107/2009 on the placing on the market of plant protection products (PPPs). The article allows the authorisation under derogation of certain hazardous substances (i.e. meeting certain hazard cut-off criteria), where such solutions are needed to address a “*serious danger to plant health*”. Despite the drastic depletion of available plant protection solutions and the critical gaps in the farmers toolbox, the current derogation mechanism has never been successfully used to approve a substance due to its unworkability and its failure to account for agroeconomic realities when assessing the availability of alternatives (cost, efficacy, scalability, machinery implications, etc.).

The proposed amendments have the potential to make the system more workable and introduce agronomic considerations into decision-making, thus ensuring that indispensable crop protection solutions that can be used safely are not removed from the market. In parallel, more workable transition timelines (“grace conditions”) have been introduced for substances losing registration without clearly identified alternatives. For such substances, product sales could continue for up to 12 months, while at the end-user level products could be used up to 24 months.

## Increased Flexibility for Derogation Submissions

Since the entry into force of Regulation 1107/2009, the derogation mechanism set out in Article 4(7) has never been successfully applied to safeguard critical uses of active substances. This has been primarily due to (i) procedural inflexibility, as derogations must be fully substantiated and submitted as part of the renewal dossier, and (ii) an unduly low threshold for considering technologies as viable alternatives to the substance or use at risk of being lost.

CLE welcomes the proposals of the European Commission to give practical effect to the principle of “No ban without alternatives” through a revision of Article 4(7), introducing provisions to make sure that essential tools remain available to the farmer's toolbox. The revised text allows applications for derogation to be submitted during the evaluation of the approval or renewal dossier. This is a substantial improvement that acknowledges

the reality that critical areas of concern cannot always be anticipated at the time of submission, and a more agile approach is required to safeguard essential product uses through the derogation process.

The scientific information and the socioeconomic and agro-economic relevance of an active substance is dynamic and has to be judged in the most recent and relevant context.

Furthermore, the exposure mitigation measures that are essential to achieving the required level of exposure minimisation change over time as practices, technologies, and scientific understanding evolve. Consequently, the essentiality of its use can only be accurately assessed now when farmers are at risk of losing access to it.

### **Strengthening the evaluation process for derogation applications: the agro-economic assessment**

The Omnibus expands the evaluation criteria to plant production, recognising the interdependence of biological efficacy, agronomic feasibility, and agro-economic sustainability.

To ensure decisions are robust, transparent, and aligned with the expanded scope of Article 4(7), the evaluation of potential alternatives needs to reflect:

- technical feasibility and scalability of alternatives at farm level considering specific conditions of crop protection and potential crop losses,
- cost and yield implications for farmers,
- operational constraints and additional investments (machinery implications, labour implications, impact on IPM – systems and resistance management programs),
- uneven availability of alternatives across crops and Member States and transition periods needed,
- economic impact on the whole Agri-chain (processing sector, etc).

CLE strongly supports this change, while recognising that, in due course, clear and robust guidance must be developed to enable applicants to substantiate, and authorities to consistently assess essentiality for production. This guidance should be complemented by the establishment of a dedicated panel, coordinated by DG AGRI and relevant scientific (national) expertise. Procedurally, the agro-economic assessment should be part of the decision-making process, and aims to establish, under realistic conditions of crop protection, the need for derogation.

Such evaluation should consider all registered uses in all EU Member States (including minor uses) rather than only considering the “representative uses” in the initial submission. This ensures that essential use decisions fully reflect farm level- realities and EU food production needs. At the same time, EFSA’s Plant Health Unit retains responsibility for the technical assessment of the application for derogation.

### **Systematic extension of the grace period**

The Omnibus proposal introduces transitional timelines (“grace conditions”) for substances that lose approval. Under these provisions, product sales could continue for up to 12 months and use by end users could be permitted for up to 24 months.

The proposed text in Article 20 conditioning the grace periods to absence of alternatives, will inevitably introduce additional complexity and will trigger assessments that resemble, in practice, a derogation-like evaluation, which would add complexity and duplication rather than simplification of decision-making processes.

Grace conditions are justified from a crop protection availability perspective: predictability of crop protection strategy for upcoming cropping seasons; management of PPP stocks and the need for transition allowing farmers to replace certain solutions. Such extended grace conditions should apply systematically to all substances with a non-renewal decision, unless withdrawal is based on serious concerns for human health or environment protection. Such an approach would support a more orderly and responsible phaseout, while allowing sufficient time to implement mitigation strategies and safeguard the integrity of the plant protection toolbox.