‘Food and feed safety omnibus’ threatens pesticide rules

Overview

The European Commission’s leaked draft proposal for the ‘food and feed safety omnibus’ proposes significant weakening of the approval and authorisation system for active substances and pesticide products in place under the current Pesticide Regulation (1107/2009). The most prominent and alarming proposal is the shift toward **unlimited approvals and authorisations**, except in narrowly defined cases. The proposal is made without an impact assessment and is absolutely disproportionate to the stated objective of the omnibus exercise to ‘simplify’ regulation, while it clashes with the announced objective of maintaining a high level of protection.

The proposal undermines the primary purpose of the regulation, which is to ensure a high level of protection based on the precautionary principle. If implemented as currently drafted, the changes would represent a **serious step backwards for pesticide regulation in the EU, potentially allowing hazardous substances to remain in use indefinitely. It would also run counter to citizens’ consistent and long-standing demands for stricter pesticide regulation and phase out of synthetic pesticides.**

Approval duration

Currently, first approvals of synthetic active substances are limited to 10 years, and renewals extend for up to 15 years. This provides a periodic point for toxicity review. According to the European Commission’s 2020 REFIT report on the implementation of pesticide legislation, this periodic review process, together with strict approval criteria, has helped increase the level of protection in the EU.

Under the draft, this system would be removed and approvals and renewals would instead be unlimited for the overwhelming majority of substances, except candidates for substitution, Article 4(7) approvals, or a few limited-period cases decided by the Commission, EFSA and Member States (see next point). Similarly, authorisations for pesticide products containing active substances with unlimited approval would also become unlimited.

Renewal currently represents the **only point at which companies are automatically required to submit a comprehensive and up-to-date dataset** covering toxicological, ecotoxicological, and environmental information.

Active substances identified as candidates for substitution (CfS) account for only around 10% of approved substances, while no substances are currently approved under Article 4(7). As a result, **under the Commission's draft proposal, 90% of active substances would receive unlimited approval**. Substances such as glyphosate, the neonicotinoid acetamiprid and two thirds of the approved PFAS pesticides would be subject to unlimited renewal.

It is very common for substances that were initially approved in the EU to later be considered harmful during their renewal process, as more scientific data becomes available. **Candidates for substitution have accounted for only one fourth (27.8%) of the substances banned under the Pesticide Regulation since 2011**. Thirty-one substances that had been banned during renewal procedures, including the reprotoxic and endocrine-disrupting mancozeb, the neurotoxic chlorpyrifos, and bee-harmful neonicotinoids, were nonetheless approved as 'regular' synthetic active substances rather than being designated as candidates for substitution, showing that this category does not capture all harmful pesticides. Most of these approved "regular" substances are now classified as carcinogenic, mutagenic, or toxic for reproduction (CMRs), identified as endocrine disruptors, or pose significant risks to workers, non-target organisms, or groundwater. The detailed figures are provided in the annex to this document. If the proposed approach in the draft, unlimited approval, had been in place since 2011, it is highly likely that these harmful substances would not have been identified and would still be on the market today.

One argument put forward by the Commission to justify this new system is that new active substances are expected to have improved toxicological and ecotoxicological properties. However, reality presents a different picture. **Among the new active substances currently under assessment and awaiting approval, several exhibit harmful properties**, such as the PFAS and potential TFA precursor fluazaindolizine or the suspected carcinogenic metyltetraprole. Likewise, 'new' substances recently put on the market, such as the bee-toxic sulfloxaflor, have been found to be harmful and restricted quickly after their first approval.

Beyond this general rule of unlimited approval, the draft gives the Commission, EFSA, and Member States broad discretion to decide which substances may be selected to undergo renewal procedures, based on available information and resources. Without the automatic requirement for the industry to submit updated toxicity data at the time of renewal, it is likely that **only limited new information about the substances will be produced over time, mostly thanks to independent scientific literature, reporting their toxicity to humans or the environment.** It is therefore unclear how many substances could be covered by such a process. Moreover, this approach would allow harm to occur before a substance's authorization is withdrawn, which is unacceptable. Furthermore, the timeline for reassessment would be at the discretion of the Commission and Member States, potentially allowing substances to remain on the market for years without adequate evaluation. With the involvement of Member States and the requirement for their approval in SCoPAFF of the list of selected substances, this process **risks being influenced by political and resource-driven considerations**, rather than remaining strictly science-based.

Approval by derogation to the safety criteria

Under the current Regulation 1107/2009, Article 4(7) allows for a **very narrow and exceptional derogation**: an active substance that does not meet the safety approval criteria may still be approved for a strictly limited period of five years, but only if it can be demonstrated, based on documented evidence that there is a serious danger to plant health which cannot be contained by any other available means, including non-chemical alternatives. In practice, this derogation has **never been used**, because in no case has it been proven that an active substance was truly essential and that no alternative solution existed.

The proposal "clarifies" that Article 4(7) cannot apply to Carcinogenic, Mutagenic and Toxic for reproduction (CMR) Categories 1A/1B, Persistent Organic Pollutant (POP), Persistent, Bioaccumulative and Toxic (PBT), or very Persistent and very Bioaccumulative (vPvB) substances. This restriction, however, **does not cover endocrine-disrupting substances**, which fall under the cut-off criteria in the same way as substances classified under CMR 1A/1B, POP, PBT, or vPvB.

Moreover, while this scope's restriction appears positive at first glance, the drafting simultaneously broadens the scope by introducing the concept of substances necessary not only for plant health but also for **plant production**. This means Article 4(7) could be invoked when production (yield) levels are at risk, including for economic reasons. This amendment runs directly **against Recital 24**, which states that **the objective of ensuring a high level of protection for human and animal health and the environment must take priority over the objective of improving plant production**.

Use of "Latest Scientific and Technical Knowledge"

The proposal introduces a highly restrictive interpretation of what constitutes the "latest scientific and technical knowledge" for the purposes of product authorisation, **directly contradicting recent EU case law**. A recent preliminary ruling by the Court of Justice of the European Union clarified that Member States are obliged to consider the most up-to-date scientific evidence when assessing the authorisation of pesticide products. In another recent ruling, the French States was recently held accountable for ecological harm resulting from outdated and inadequate pesticide environmental risk assessments, and obliged to review authorisation in light of the latest science. Under the amended text, however, Member States would be required to rely **exclusively on "the last assessment conducted at EU level"** for the active substance.

In practice, this would **severely limit the ability of Member States to respond to emerging science**. EU-level assessments may be several years old at the time of a national product authorisation. By freezing the scientific basis of evaluations to the date of the last EU assessment, Member States would be prevented from incorporating new peer-reviewed studies or other evidence of risks. Under such a system, **Denmark, for example, would not have been able to ban PFAS pesticides**, as it recently did.

Grace periods

The proposal **significantly increases the maximum overall length of grace periods to three years**: two years for the sale and distribution of products, plus an additional year for disposal, storage, and use of existing stocks. Under the current Article 20(2), the maximum grace period is 18 months, and this applies only when the non-renewal does not concern protection of human health, animal health, or the environment. Yet in practice, harmful substances such as endocrine disruptors have still been granted grace periods of 9 to 18 months (e.g., the recent case of flufenacet), in clear violation of the Regulation.

The Commission's proposal would **legalise and extend these delays**, further postponing the removal of unsafe products from the market. Crucially, the three-year grace period **could also apply to substances that fail to meet safety criteria**, unless they pose immediate and serious risks. This reflects the framework of Article 69, which is intended to allow immediate action in such cases, but according to our knowledge, no substance has ever been considered as meeting the conditions to trigger Article 69.

EFSA support to rapporteur Member States

The proposed changes to Article 11 would allow **Rapporteur Member States to request scientific and technical support from EFSA during their assessment** of active substances. For biocontrol substances, approval applications could directly be submitted to EFSA. This is a constructive change that could improve consistency and quality of the assessments.

Hazard-based approach undermined

However, the strengthened role of EFSA does not compensate for the **deletion of the requirement to halt assessments when cut-off criteria are met**. Currently, when an active substance is identified as CMR 1A/1B, POP, PBT, vPvB, or an endocrine disruptor affecting humans or non-target organisms, the assessment must be immediately stopped, in line with the hazard-based approach established under the pesticide regulation. Removing this obligation would **undermine this protective and resource-saving approach**, prolong the regulatory process and the presence on the EU market of harmful substances.

Minor uses

The EU definition of 'minor use' for pesticide products, set out in Article 3(26) of Regulation 1107/2009, is overly broad and gives Member States wide discretion to decide which uses qualify as 'minor' (e.g., crops grown on a small scale or widely grown but needed exceptionally for plant protection). The current omnibus proposal does not clarify this definition; instead, it makes it easier to authorise substances for minor uses. By removing the 'public interest' requirement, allowing minor-use authorisations even when the use is not minor in the reference Member State, and creating a legal obligation for Member States to support minor-use extensions, the **proposal opens the door to their misuse**. Minor-use designations could be applied without crop- and climate-specific risk assessments, potentially increasing exposure and

potentially putting human health and the environment at risk. The only positive proposal is that the minor-use lists would have to be made publicly available by Member States.

Mutual recognition

The proposed changes of the Regulation introduce several changes to the mutual recognition system. Positively, they require that a product must actually be placed on the market in the reference Member State, helping prevent abuse of the system to circumvent higher fees. However, the proposal also makes it easier for official or scientific bodies and professional agricultural organisations to apply for mutual recognition without demonstrating public interest, expands the types of eligible uses, and reduces documentation and assessment requirements for certain applications (biocontrol and low-risk substances). Lastly, the proposal introduces the possibility for detailed implementation rules to be adopted by the EU Commission *via* implementing regulation. It remains unclear what these rules would entail.

Rules applicable to biocontrol

The European Commission's draft proposal for the omnibus revision of the pesticide regulation includes several measures aimed at facilitating market access for biocontrol products. This objective is welcome, as biocontrol plays a key role in Integrated Pest Management and is essential for phasing out synthetic pesticides. At the same time, several elements of the proposed changes risk compromising safety, scientific integrity, and data transparency. Accelerated access for biocontrol products should be pursued through strengthening assessment capacity, maintaining robust risk evaluation, and ensuring comprehensive monitoring.

The draft introduces a **definition of biocontrol active substances**, describing them as micro-organisms, naturally occurring inorganic substances (excluding heavy metals and their salts), or substances of biological origin or produced synthetically that are functionally identical and *structurally similar* to natural substances. This definition, however, is problematic. To ensure that biocontrol remains restricted to a select and safe group of substances, "**identical" must be clearly defined**. It should require that the substance contains only naturally occurring amino acids, that its three-dimensional molecular structure is identical to the natural substance, that its function is identical, and that it is biologically degraded through predictable, natural pathways. Without these clarifications, there is a risk of widening the category to synthetically produced substances that may have unknown or harmful effects.

The draft also proposes requiring Member States to prioritise the assessment of biocontrol substances. **This should not result in further delays** in the evaluation of synthetic substances.

The draft also proposes **provisional authorisation.** While faster access to biocontrol products is desirable, natural substances, particularly microbial organisms, can present risks. Microbials have the potential to survive, multiply, move, and colonise new environments, with possible

unintended impacts on biodiversity. These characteristics make a robust risk assessment essential prior to authorising their use. Additionally, the proposal introduces a **single zonal system with automatic mutual recognition to ease authorisations.** However, the combination of reduced documentation requirements and automatic authorisation after 120 days increases the risk that products could be approved without sufficient safety review.

The draft r**emoves the obligation to keep records of biocontrol product use**. Such records are critical to monitor trends, assess environmental and health impacts, and inform policy decisions. Even natural substances can have unexpected harmful effects, and comprehensive data collection is essential for timely detection and management of any risks.

Conclusion

The cumulative effect of these changes is deeply concerning. The draft proposal **significantly weakens the EU pesticide regulatory framework**. Most active substances could remain on the market for decades without reassessment, creating the potential for prolonged exposure to harmful chemicals. The proposal increases the likelihood of political considerations influencing safety evaluations and undermines the precautionary principle that ensures high levels of protection for humans, non-target organisms, and the environment.

Recommendations

In its 2020's report on the assessment of the implementation of the Pesticide Regulation (REFIT), the European Commission recognised that the regulation is largely effective in protecting human health and the environment, thanks to the stringency of its approval criteria and the regular review of the approval of all active substances. Nevertheless, the Commission also acknowledges significant delays in the regulatory process and provides recommendations, which we consider the way forward today.

- "In line with the views of the European Parliament to avoid procedural delays leading to inefficiencies, the Commission recommends that **Member States only accept complete dossiers of high quality as admissible** - both for applications for first or renewed approval of active substance and PPP authorisation applications.
- The fees raised by some Member States seem to be both insufficient to cover their costs, and, in addition, not all Member States ring-fence the fees for the authorities actually carrying out the work, resulting in insufficient resources being available. In order to have the required resources available, **Member States should review the fees they charge, set them at a level fully recovering their costs, and ensure that the fees benefit the authorities conducting the work**.
- The Commission will consider opening **infringement proceedings** against those Member States that systematically fail to respect the legal deadlines.
- Member States should only continue the **full risk assessment if either the active substances do not meet the cut-off criteria** or at least one of the derogation possibilities for their approval is invoked."

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Pesticide Action Network (PAN Europe) is a network of NGOs working to reduce the use of hazardous pesticides and have them replaced with ecologically sound alternatives. We work to eliminate dependency on chemical pesticides and to support safe sustainable pest control methods. Our network brings together over 45 consumer, public health and environmental organisations and women's groups from across Europe.

Annex: statistics on EU-banned active substances

162 substances banned since 2011, including:

- 45 Candidates for Substitution (27.8%)
- 117 non-Candidates for Substitution (72.2%)

Reason for the ban	Overall number of substances	CfS substances	Non-CfS substances
Abandonment The approval has expired, and no renewal application has been submitted OR The approval has expired, and a renewal application was submitted but later withdrawn. OR Confirmatory information incomplete or not provided	**108 (66,7%)**	**26**	**82**
Reason other than abandonment	**54 (33,3%)**	**19**	**35**
A risk was identified during the re-assessment process			31

A risk was identified under Article 21			1
Reason unknown			3

Of the 31 substances banned due to an identified risk during re-evaluation:

- 10 are CMRs, plus 1 substance with a metabolite that is CMR
- 7 are endocrine disruptors, plus 1 substance with a metabolite that is PE
- 7 pose a health risk (to workers, residents, or consumers)
- 17 pose a risk to non-target organisms
- 9 pose a risk to groundwater