



## Joint position on the draft parliamentary report and tabled amendments on the Food and Feed Safety Omnibus

The Commission's proposal for a "Food and Feed Safety Simplification Omnibus" already represents a [significant weakening](#) of the EU's pesticide safety framework established under Regulation (EC) No 1107/2009. Far from being a technical simplification exercise, the proposal removes important safeguards designed to protect human health and the environment from pesticides, including the system of periodic reassessment of pesticide toxicity. **The proposal has raised tremendous concerns among the scientific community and civil society.**

Rather than restoring and strengthening the safety rules established under EU pesticide legislation, the draft report by Members of the European Parliament Herbert Dorfmann (EPP) and Michele Picaro (ECR), together with several tabled amendments, would go even further in weakening these safeguards. This would move the framework further away from its fundamental

purpose: ensuring a high level of protection of human and animal health and the environment, based on the precautionary principle and robust, independent scientific assessment.

We are particularly concerned that:

- **Active substances, and the products containing them, could remain on the market indefinitely**, while meaningful periodic reassessment of their toxicity would be removed.
- The possibility of triggering a targeted reassessment of substances with unlimited approval would become highly exceptional, meaning that **new scientific evidence might not lead to regulatory action until significant evidence of harm has accumulated**. This undermines the precautionary principle at the heart of EU pesticide legislation.
- **Member States would lose important rights and responsibilities to conduct meaningful scientific scrutiny** of pesticide products placed on their markets, including their ability to take account of the latest scientific evidence and to refuse authorisations where legitimate health or environmental concerns exist. This clearly violates Member States' right to adopt more stringent environmental measures, in accordance with the EU Treaties.
- **Tacit authorisations and automatic mutual recognition would further reduce national scrutiny** and could allow pesticide products onto the market without a substantive assessment by the competent authority.
- **Risk mitigation measures could be used as a mechanism to keep substances on the market** even where the regulatory safety criteria for approval are not met.
- Derogations, extended grace periods and emergency authorisations would be broadened, creating **routes for hazardous substances that should no longer be approved to remain in use**.
- The EU would facilitate the export of seeds treated with pesticides whose use it prohibits on its own territory.
- The proposed changes would also weaken transparency and access to information on pesticide use.

The European Parliament should not allow the simplification agenda to become a backdoor for weakening pesticide safety. **Our primary call is for Members of the European Parliament to reject the proposal as a whole.** If it nevertheless proceeds, we urge MEPs to oppose amendments that would weaken existing safeguards and to support amendments that protect and strengthen pesticide safety standards.

## Unlimited approval (Articles 5, 14)

### ❖ We strongly oppose proposals to grant unlimited approval for active substances.

Periodic reassessment is an essential regulatory safeguard. The fact that a substance was considered acceptable at one point in time cannot justify assuming that it will remain safe indefinitely **or for the next 25 years**. Scientific knowledge evolves and new evidence becomes available, including evidence on effects that may not have been adequately identified at the time of the initial approval, such as neurotoxicity.

The experience of the EU regulatory system demonstrates why periodic review is necessary. Since 2011, the renewal process has resulted in the non-approval or withdrawal of 54 active substances because of identified risks to human health or the environment. Importantly, 31 of these substances had not previously been identified as candidates for substitution. This demonstrates that **periodic reassessment is not a redundant administrative exercise. It is an essential mechanism for detecting risks that were not sufficiently understood or identified when substances were initially approved**. Unlimited approval would therefore amount to abandoning one of the EU pesticide framework's important mechanisms for responding to evolving scientific knowledge.

Periodic review also ensures that the responsibility for demonstrating continued safety remains with the companies placing substances on the market. This is consistent with the polluter-pays principle. Reversing this system would mean that taxpayers and public institutions would increasingly bear the costs of identifying new hazards.

**We are also deeply concerned by the rapporteur's proposal to grant unlimited approval to active substances whose renewal assessments are already underway.** This would affect around 200 ongoing renewal procedures, including the reassessment of PFAS pesticides that degrade into the forever pollutant trifluoroacetic acid (TFA), for which a classification as toxic for reproduction category 1B has been recommended by the European Chemicals Agency (ECHA). Beyond the concerns for human health and the environment, such a change would amount to a significant **waste of regulatory resources, time and public and private investment** already devoted to these assessments.

### ❖ We also oppose proposals to grant unlimited approval for biocontrol substances or low-risk substances.

While we agree that market access for biocontrol products should be accelerated, this should not come at the expense of proportionate safety safeguards. Although these products are generally considered lower risk, they may still have significant impacts on the environment and potentially on human health. It is therefore important to ensure that they undergo regular assessment.

Natural substances, including bacteria, fungi, protozoans, viruses, viroids, peptides, mycoplasmas and related materials such as living or dead cells, microbial metabolites,

fermentation materials and cell fragments, **cannot be presumed to be harmless simply because they are naturally occurring or biological in origin.** They may have adverse effects on human health, namely unexpected immune reactions. For living organisms, environmental assessment presents additional challenges because they may survive, multiply, disperse and colonise environments beyond the intended area of application. Currently, many aspects remain unknown (e.g. their fate in the environment, impacts on biodiversity). Researchers underline the need for field studies and thorough assessment of the impacts on non-target organisms.

We support amendments that maintain the current system of **10** years for first approval; and **15** years for renewal.

We recommend particularly deleting amendment 35.

### **Targeted reassessment (Articles 18-18a)**

The current proposal already grants the Commission considerable discretion to trigger the reassessment of a substance with unlimited approval when new scientific evidence emerges or when Member States raise concerns. There is a significant risk that the evidence threshold for triggering reassessment could be excessively high, meaning that regulatory action would only occur **once substantial evidence of harm has accumulated**, rather than when credible indications of concern emerge. This would be inconsistent with the precautionary principle, which underpins the EU pesticide regulatory framework.

We are therefore particularly concerned by proposals from the rapporteurs and other MEPs that targeted reassessment could be triggered only by “broad-ranging indications of significant safety concerns”. This would make reassessment of substances with unlimited approval not only exceptional in law, but potentially extremely difficult to trigger in practice. Combined with unlimited product approvals, as proposed by the rapporteurs, **this creates a system in which substances and products can remain on the market indefinitely while the possibility of meaningful toxicity reassessment becomes remote.**

We support amendments that **oblige the Commission to take action within a defined timeframe when objective criteria, such as new monitoring data or a Member State request, indicate that a concern has arisen.**

We recommend particularly deleting amendments 25-29.

## **Approval criteria and risk mitigation measures (Articles 4(1)-(3), 29)**

We are concerned by amendments that would explicitly require risk mitigation measures and precision techniques to be taken into account when determining whether the approval criteria are met, both in relation to substance approval and product authorisations.

Risk mitigation should not become a mechanism for keeping substances on the market where the safety criteria for approval are not met. Particularly because the effectiveness of such measures cannot simply be assumed. Their practical feasibility, enforceability and real-world effectiveness must be assessed and demonstrated, which is already not the case today as confirmed by the EU Court of Justice (Cypermethrin case C-316/24 P). The absence of an effective post-market monitoring system further limits the ability to rely on risk mitigation measures.

We recommend deleting this proposal, particularly amendments 14, 15, 38 and 39, which falls outside of the scope of the proposal.

## **Derogations (Articles 4(7))**

The Commission proposal already significantly broadens the scope of the derogation provisions. We are particularly concerned by the approach proposed in the rapporteur's draft report, under which decisions would be based on a “socio-economic and agro-economic assessment” and taken within three months of EFSA's conclusions. This contradicts the clear hierarchy of objectives: a high level of protection of human and animal health and the environment must take precedence over considerations relating to plant production (Case C-162/21).

Moreover, Maximum Residue Levels should not be maintained to facilitate derogations. Once a substance is found not to meet the safety criteria, to pose risks to human health or to have unacceptable effects on the environment, its MRLs should be automatically lowered to the limit of quantification (LOQ).

We support amendments that:

- delete references that make plant production a justification for derogation;
- replace “reasonable” alternatives with “available” alternatives
- exclude additional substances of particular concern from the derogation scope, including endocrine disrupting substances;
- restore phase-out plans.

We recommend particularly deleting amendments 17-22.

## Grace periods (Articles 20, 46)

We oppose the rapporteurs proposal that would systematically extend grace periods to three years for all substances (two years for sale and distribution, one year for use). The Commission proposal already extends grace periods to three years where no alternatives are available. **A blanket three-year grace period would prolong the use and environmental release of substances that have already failed to meet the conditions for continued approval.** This is particularly concerning for substances with very hazardous or persistent properties. For example, PFAS pesticides degrade into reprotoxic (1b), very mobile and very persistent (vPvM) trifluoroacetic acid (TFA). Allowing continued use for several additional years will intentionally prolong contamination of groundwater.

We support amendments that:

- state that no grace period shall be established where the substance non-renewal is due to concerns for human health or the environment, particularly if the substance meets one of the “cut-off” criteria of the Pesticide Regulation;
- delete the possibility to grant grace periods of up to three years.

We recommend particularly deleting amendments 30, 31, 57 and 58.

## Candidates for substitution (Article 24)

The rapporteur proposes extending the approval period from seven to 15 years and basing renewal decisions on a “socio-economic and agro-economic assessment”. These changes fall outside the scope of the Commission proposal. Candidates for substitution are more hazardous active substances approved in the EU under Article 24 and Annex II. This category includes, among others, substances classified as carcinogenic or toxic for reproduction category 1B but approved on the basis of negligible exposure (i.e. no human contact), such as 8-hydroxyquinoline.

The purpose of the candidate-for-substitution regime is precisely to subject more hazardous substances to enhanced scrutiny and to encourage their replacement where safer alternatives are available. Extending their approval period from seven to 15 years would run directly counter to this objective, and would strip the designation of any meaningful regulatory consequence.

We recommend deleting this proposal, particularly amendments 33 and 34, which falls outside of the scope of the proposal.

## National product authorisations

We are extremely concerned by a series of proposals that would remove Member States' **rights and responsibilities to conduct meaningful scientific scrutiny of products placed on their markets and reduce their ability to identify or act on new risks once an active substance has been approved.**

These proposals undermine a principle expressly recognised by Article 193 TFEU that Union environmental measures shall not prevent any Member State from maintaining or introducing more stringent protective measures.

- **Unlimited authorisations (Article 32):** Periodic reassessment of pesticide formulations is just as essential as the periodic reassessment of active substances. It becomes even more critical in a system where active substances could receive unlimited approval, as the product authorisation process may become the only remaining moment where the industry is required to provide updated data and for authorities to identify new risks. Product assessment is also essential for identifying unacceptable co-formulants, as required by the Regulation. Moreover, important aspects of product safety assessment, including the assessment of synergistic effects, and long-term toxicity and carcinogenicity, are not yet implemented (Blaise case C-616/17). These requirements should be properly applied, rather than further weakening product-level scrutiny. **Unlimited product authorisations should therefore be rejected (particularly amendments 45, 46, 47).**
- **Latest scientific knowledge (Article 36):** The Commission proposal would require Member States to rely on the latest EU-level assessment when assessing pesticide products, preventing national authorities from taking into account new scientific evidence or concerns identified after the EU-level assessment. This is inconsistent with both EU case law (Cases C-308/22, 309/22, 310/22) and recent national case law<sup>1</sup>, which have established that Member States must take into account the most up-to-date scientific and technical knowledge. The rapporteur's proposal would further restrict Member States' ability to do so by requiring them to rely on the latest EFSA conclusions and the agreed list of endpoints underpinning the approval. Moreover, where a Member State identifies new concerns and notifies the Commission accordingly, the rapporteur proposes that the relevant application for product authorisation should not be suspended, postponed or withdrawn on this basis. **This would further weaken the ability of national authorities to act when new concerns emerge and should therefore be rejected. We recommend deleting amendments 49, 50 and 51.**
- **Tacit authorisations (Article 37):** We oppose proposals under which an authorisation should be deemed granted simply because an authority has not completed its

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<sup>1</sup>[French court of appeal orders French government to review environmental toxicity of hundreds of pesticide authorisations within 24 months; EU Member States need to revise their pesticide authorisation process: Dutch court orders ban on endocrine-disrupting pesticide formulation | PAN Europe](#)

assessment within a specified period. This creates an unacceptable risk that products will enter the market without a meaningful assessment of their toxicity, including their long-term toxicity and carcinogenicity as required by EU law (cf. C-616/17). **We therefore strongly oppose tacit authorisation, as proposed in amendment 52.**

- **Automatic mutual recognition (Article 40):** This means authorisation granted in one Member State would automatically apply throughout the same geographical zone. This proposal would strip Member States from their right to prevent products from being authorised where there are legitimate and scientifically substantiated concerns. **We oppose automatic mutual recognition, as proposed in amendments 54 and 55 by the rapporteurs.**

Rapporteurs are proposing that this automatic mutual recognition applies as well to **emergency authorisations** granted under Article 53. These authorisations are intended for exceptional, unforeseen and specific circumstances. This proposal, particularly amendments 63, 64 and 65 contradicts the purpose of emergency authorisations and related case law (Case C-162/21).

### **Biocontrol definition (Article 3)**

We support amendments clarifying that **only synthetic substances that are functionally and structurally identical to naturally occurring substances** should fall within the scope of the biocontrol definition. This clarification is essential to prevent the category from being extended to synthetically produced substances with harmful effects, including pyrethroids, or to organisms/micro-organisms genetically modified.

We do not support the **inclusion of heavy metals and their salts**, including copper compounds, within an expanded definition of biocontrol substances. Copper is approved as a candidate for substitution because of its persistence and toxicity. There are indeed well-established environmental concerns associated with the use of copper-based fungicides, including impacts on terrestrial and aquatic biodiversity and ecosystem functions. Copper exposure can, for example, adversely affect microbial communities. It would therefore be contradictory to classify a substance identified by the EU regulatory system as being of greater concern as “biocontrol”.

We therefore support amendments that:

- clarify that only synthetic substances that are functionally and structurally identical to naturally occurring substances qualify as biocontrol.
- exclude heavy metals and their salts from the biocontrol definition.

## **Access to records (Article 67)**

According to the rapporteur's draft report, producers would no longer be required to provide pesticide use records. Moreover, the right of third parties, such as water providers and residents, to request access to pesticide records would be removed. This runs counter to the public interest right in accessing information on emissions in the environment, including the nature and the quantity of those emissions (Case T-329/1).

We recommend opposing the rapporteur's proposal to restrict the access to pesticide use records, particularly amendments 69 and 70.

## **Seed treatment (Article 49)**

The Commission's proposal to explicitly clarify that the sowing of treated seeds constitutes a use of plant protection products is a positive and necessary step. It would ensure that the record-keeping obligations under Article 67 also apply to the use of pesticide-treated seeds. The rapporteurs' proposal to delete this clarification is therefore highly concerning. Data on the use of treated seeds are currently limited, despite the potential for pesticide-treated seeds to result in significant environmental exposure, including through dust, soil and water contamination, as well as exposure to non-target organisms.

It is important to stress that treating seeds pre-emptively results in pesticide use irrespective of whether a pest problem is present or whether treatment is necessary, and therefore runs counter to the Integrated Pest Management (IPM) principles of the Sustainable Use of Pesticides (SUD) Directive. The latter requires prioritising prevention, monitoring and the use of non-chemical methods, with chemical pesticides used only where necessary and in a targeted manner.

Moreover, we strongly oppose allowing seeds intended for export to third countries to be treated with plant protection products that are not authorised in the EU. Such a provision would enable the use of pesticides deemed unacceptable under EU safety standards, while exposing workers and the environment in third countries.

We support retaining the Commission's proposal and ensuring that the use of treated seeds is fully covered by record-keeping obligations.

We recommend opposing the rapporteurs' amendments 37 and 59.

## Drones

We are deeply concerned by the rapporteurs' proposals to further relax restrictions on pesticide spraying by drones. These include allowing Member States to introduce horizontal exemptions for professional users pending the adoption of a delegated act; requiring the Commission to adopt that act within one year, rather than the four years proposed by the Commission; and replacing prior approval of application plans with a simple prior notification for low-risk substances. Such changes risk expanding drone use before its impacts have been adequately assessed.

Aerial pesticide application can cause significant harm to human health and the environment, particularly through spray drift. **The available evidence raises specific concerns about drone spraying:** studies have reported increased droplet drift and significantly higher bee mortality compared with ground-based application ([study](#)). Researchers also highlight major knowledge gaps regarding impacts on humans and other organisms. The OECD has likewise stressed that potential benefits cannot be realised without robust assessment ([OECD report](#)). **In the absence of a comprehensive, evidence-based assessment, there is no sound basis for broadening exemptions from the prohibition on aerial spraying.**

We therefore call for a comprehensive impact assessment, based on robust data, including data on exposure and spray drift, and the development of specific guidance for assessing the risks of pesticides applied using unmanned aircraft systems before any derogations are considered. Any future derogations should be limited to specific unmanned aircraft systems and strictly defined conditions, and permitted only where evidence demonstrates clear advantages and lower risks to human health, biodiversity and the environment compared with ground-based application.

Any permitted use must also fully comply with Integrated Pest Management (IPM) principles, prioritising non-chemical methods and ensuring that pesticide use minimises risks to human health and the environment. Finally, all drone applications must be electronically recorded alongside mandatory pesticide-use records, with the resulting data made continuously and publicly accessible.

## Maximum Residue Levels (MRLs)

Under the Omnibus proposal, the Commission would be empowered to reject applications for, or revoke existing, MRLs for EU-banned pesticides that meet the Pesticides Regulation's "cut-off" criteria<sup>2</sup>.

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<sup>2</sup> These are substances that are Carcinogenic, Mutagenic and Toxic for reproduction (CMR) Categories 1A/1B, Endocrine Disruptors for humans or non-target organism, Persistent Organic Pollutant (POP), Persistent, Bioaccumulative and Toxic (PBT), or very Persistent and very Bioaccumulative (vPvB).

The rapporteurs indicate that they welcome this measure. **However, the proposal falls far short of what is needed.** It treats revocation as a derogation, leaving the general practice of permitting residues of EU-banned pesticides in imported food largely unchanged. It also makes revocation conditional on an impact assessment and covers only a limited subset of banned pesticides: [PAN Europe's analysis](#) finds that substances meeting the cut-off criteria account for just 22% of EU-banned pesticides.

**A recent JRC study provides evidence that lowering MRLs to the limit of quantification (LOQ, the “technical zero”) is both feasible and beneficial for EU agriculture.** Examining 18 substances across 235 products and 86 countries, it finds that lowering MRLs to the LOQ would not cause major disruption to the EU food market. **Instead, EU agricultural production increases across all scenarios examined, with potential gains in competitiveness for European farmers.** In the intermediate scenario, production increases by 0.23% overall, including 3.3% for citrus fruits and 3% for tomatoes and rapeseed. The study also identifies much larger increases for some products under its most favourable scenario. There are other benefits not quantified by the study: reduced exposure to hazardous pesticides and better protection for human health, biodiversity, soil, water and ecosystems. **There is no sound justification for continuing to allow residues above the LOQ of pesticides deemed too hazardous for use in the EU.**

**We therefore support amendments requiring the corresponding MRLs to be automatically revoked whenever an active substance is not approved under Regulation (EC) No 1107/2009. This must happen automatically, without requiring a separate EFSA scientific opinion. There should be no exception for active substances approved by derogation under Article 4(7) of the Pesticide Regulation.**

The Commission also proposes deleting the periodic review of MRLs by monitoring data, including where contaminants persist in the environment, such as DDT. This risks keeping obsolete MRLs in place despite evidence of ongoing contamination, thereby prolonging consumer exposure to hazardous substances and undermining consumer protection. **We oppose this deletion and call for the retention of periodic, monitoring-based reviews to ensure that MRLs remain up to date and protective of human health.**

We therefore support amendments that:

- require the corresponding MRLs to be automatically revoked whenever an active substance is not approved under Regulation (EC) No 1107/2009
- maintain the periodic review of temporary MRLs by monitoring data

**The recommendations are endorsed by the following organisations:**

**European / International organisations**

- Agroecology Europe
- APIMONDIA Federation
- BeeLife European Beekeeping Coordination
- BEUC - The European Consumer Organisation
- BirdLife Europe and Central Asia
- Child Rights International Network (CRIN)
- Corporate Europe Observatory
- European Environmental Bureau (EEB)
- European Federation of Food, Agriculture and Tourism Trade Union (EFFAT)
- Foodwatch
- Friends of the Earth Europe
- Health and Environment Alliance (HEAL)
- Humundi (formally SOS Faim)
- Pesticide Action Network Europe (PAN Europe)

**National organisations**

- Ecologistas en Acción (Spain)
- Générations Futures (France)
- Global 2000 (Austria)
- Living Earth Coalition (Poland)
- Nature & Progrès (Belgique)
- Natuur & Milieu (Netherlands)
- Pestizid Aktions-Netzwerk e.V. (Germany)
- Umweltinstitut München e.V. (Germany)

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