POLICY FORUM

ENVIRONMENTAL REGULATION

EU Omnibus proposal increases pesticide risks

More efficient environmental risk assessment and stronger protection are achievable

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The European Union (EU) has one of the most comprehensive systems for risk assessment of pesticides. However, pesticides continue to cause ecological damage and pose risks to human health (*1*). Additionally, regulatory assessments are often delayed, slowing the market entry of new substances (*2*). To address such delays and simplify procedures and requirements for pesticide marketing, the European Commission proposed an "Omnibus Simplification package" on food and feed safety on 16 December 2025. Here, we explain how implementing the Omnibus package would amplify rather than resolve shortcomings of current environmental risk assessment. This would jeopardize the Omnibus's goal to maintain high standards for the protection of human and environmental health, as well as the EU's long-term environmental objectives and international commitments to restore ecosystems. We provide actionable recommendations for improving environmental risk assessment for stronger biodiversity protection while limiting regulatory burden.

Since 2011, Regulation (EC) No 1107/2009 has been the main EU framework regulating the approval and use of pesticides to safeguard human health and the environment, strengthening the application of the precautionary principle by curbing the use of harmful substances. Active substances undergo tiered risk assessment using model species, progressing from laboratory studies to more realistic higher-tier studies when lower tiers indicate potentially unacceptable impacts. Approval relies on the manufacturers' study data, evaluated by a designated Member State and the European Food Safety Authority (EFSA), all of which inform an EU-level decision. Most active substances are approved for 10 years, with renewal applications subject to potentially updated data requirements and inclusion of independent scientific studies. Once approved, Member States may authorize plant protection products containing the substance after a separate, product- and use-specific evaluation.

Although risk assessment has been progressively improved, considerable shortcomings remain. For instance, impacts on many nontarget organisms such as fungi, amphibians, reptiles, and bats are not assessed, and insufficient consideration is given to sublethal and indirect effects (see the box). The combined effects of multiple pesticides applied simultaneously or sequentially on the same or nearby fields are not accounted for in premarket risk assessments, despite extensive evidence for additive, synergistic, and cumulative toxicity (*3*). Higher-tier studies often lack statistical power, limiting the reliability of safety conclusions. For example, none of 63 higher-tier neonicotinoid studies achieved the 80% power recommended by EFSA to detect a 7% reduction in honey bee colony size (*4*).

THE PROPOSED OMNIBUS PACKAGE

The Omnibus proposal's amendments to Regulation 1107/2009 would exacerbate shortcomings of the current environmental risk assessment and approval system (see the box). Most notably, it would grant indefinite approval to most active substances currently on the market or approved in the future, aside from selected groups of substances still requiring renewals (Reg. 1107/2009, amended Art. 5).

This would raise the prospect of aforementioned risk assessment gaps and leave many substances untested under new methodologies, even though the Omnibus would require the Commission to regularly identify substances with unlimited approvals for renewal assessments (amended Art. 18), introduce targeted reassessments (new Art. 18a), and retain ad hoc reviews (Art. 21). Although selective renewals would require a full new application, targeted reassessments are foreseen as a partial application with specific criteria and defined data requirements, and ad hoc reviews respond to emerging concerns through a reopened review of the original assessment. Unlike time-bound renewals, all three leave discretion over how many and which substances are assessed, creating room for political or economic considerations to influence reassessment decisions. As the stated goal of the Omnibus is reducing regulatory burden, the overall volume of assessment would likely be considerably reduced.

The Omnibus specifies criteria for selecting substances for renewal or targeted reassessment, but these would neither make reassessment obligatory nor function as effective triggers. For instance, "relevant new or updated data requirements or guidance documents" may apply to most substances, making it a weak prioritization criterion or trigger. Additionally, "available monitoring data" presupposes a surveillance system that does not yet exist: Environmental monitoring remains sparse, pesticide use data that could inform such monitoring are largely inaccessible, and feedback mechanisms into regulatory decision-making have not been established.

Substances may also be selected based on "indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge," but this assumes such indications reliably emerge without a structured review cycle. New scientific knowledge would depend largely on a scientific community that lacks access to pesticide-use data, lacks the mandate and funding to systematically assess all substances, and whose findings are often only integrated into regulatory decision-making during renewal.

Time-bound renewal has been instrumental in removing high-risk substances from the market. Since the introduction of a harmonized EU-wide evaluation system for active substances in 2011, 59 conventional active substances have failed renewal for health or environmental concerns, and renewal was not sought for an additional 96, likely in part because applicants anticipated nonrenewal. Over the same period, approximately the same number of substances were approved or reapproved (161). Only two substances were withdrawn through 14 ad hoc reviews.

Rather than fostering sustainability and innovation, as claimed in the Omnibus, the removal of time-bound substance renewals would slow the identification of harmful substances and prolong their use, reducing incentives to develop safer pest-control alternatives, in-

cluding lower-risk chemical and biological alternatives, more resilient crop varieties, and technical innovations.

To prevent plant protection product authorizations from becoming indefinite where they contain only indefinitely approved active substances, the Omnibus would limit product authorizations to 15 years. However, the effectiveness of product evaluations would be undermined by a weakened integration of new independent knowledge. Although Article 36(1) requires product assessments to consider "current scientific and technical knowledge," the Omnibus would redefine this term to refer primarily to "the latest active substance assessments at Union level." In practice, this would, in many cases, remove the obligation to consider independent research published after substance approval. Moreover Member States would lose the autonomy to act on such research. They may request a reassessment at EU level, but the decision to reassess would remain entirely with the Commission [amended Art. 36(1)]. This potentially leads to regulatory assessments that diverge from the current state of scientific knowledge—a concern that only grows if active substance approvals become indefinite.

Furthermore, the Omnibus would broaden the legal basis for grace periods [amended Art. 20(2) & Art. 46] during which products containing substances whose approval has not been renewed may still be sold and used to exhaust existing stocks. Regulation 1107/2009 allows grace periods of up to 18 months but calls for immediate withdrawal where nonapproval is due to "immediate concerns for human health or animal health or the environment." In practice, however, the Commission and Member States have frequently granted grace periods even in cases involving identified health or environmental concerns, adopting a weight-of-evidence approach to determining the level of acceptable risk. The Omnibus would broaden the circumstances under which grace periods may be granted, including cases involving identified health or environmental concerns, unless these are considered "immediate and serious." In addition, the proposal would permit grace periods of up to 3 years where no "reasonable" alternatives are considered available.

The Omnibus would also reduce requirements for labeling active substances as "low risk" (amended Art. 22) and use a one-zone rather than three-geographic-zone authorization system for products containing only these active substances [amended Art. 33(2)]. In current product authorization, applicants choose the evaluating Member State within a zone, whose decision applies zone-wide unless other Member States object on specific environmental or agricultural grounds. Germany's Federal Agency for Nature Conservation and others have criticized the system for enabling selective applications in Member States with less stringent assessment practices and for imposing excessively high requirements for deviating from the evaluating Member State's decisions, even in cases of erroneous evaluation (*5*). Although the one-zone system is an effective streamlining measure, it amplifies those concerns. Notably, the Omnibus itself acknowledges that applicants sometimes seek authorization in Member States where they never intend to market the product, suggesting that evaluating authorities are chosen for strategic reasons.

Finally, while the Omnibus proposal contains measures to facilitate the market entry of biocontrol products, it would also remove the requirement for farmers to document their use [amended Art. 67(1)]. Yet, documentation facilitates monitoring, which is also relevant for biocontrol substances, as substantial knowledge gaps remain regarding their environmental impacts owing to limited ecotoxicological assessment. Living biocontrol agents can multiply, persist, and spread beyond their intended use (*6*). And, although most natural substances tested to date have shown low ecotoxicity, some elicit effects comparable to or exceeding those of synthetic pesticides (*6*). Moreover, the Omnibus's definition of biocontrol substances covers not only microorganisms, semiochemicals (e.g., pheromones), and inorganic naturally occurring substances (except heavy metals), but also synthetic compounds that are structurally similar or functionally identical to substances of biological origin (amended Art. 3); it is not entirely clear which synthetic compounds would fall within this definition.

In conclusion, the Omnibus would reduce regulatory burden and, in the short term, accelerate market entry by clearing renewal backlog without fundamentally changing scientific risk assessment methodologies. However, it would limit their systematic application in regulatory decisions at the expense of human and environmental health protection. Hence, it risks working against broader EU and international environmental objectives that emphasize precaution, biodiversity protection, ecosystem restoration, and reducing environmental pressures associated with pesticide use.

Furthermore, the process of producing the Omnibus is deeply concerning because of its poor and biased consideration of science and citizens, respectively. Although the Omnibus preamble acknowledges warnings from nongovernmental organizations and citizens regarding risks to human health, biodiversity, and environmental protection, the Commission deemed a formal impact assessment unnecessary, prioritizing administrative simplification and cost savings for those the Commission considered the "most directly affected stakeholders." In practice, the proposal prioritizes industry interests over environmental and public health safeguards, despite Regulation 1107/2009's principle that economic considerations should not override the protection of human health and the environment. Such a process that sidelines scientific evidence, public concern, and established law-making principles risks undermining public trust.

A dead bumble bee (*Bombus terrestris*) lies on the ground. Pesticides, one of multiple stressors threatening bees and other pollinators, can be directly regulated.

PHOTO: THERESIA KRAUSL

A SAFER PATHWAY TO REDUCE PESTICIDE HARM

Meeting international and European commitments to nature restoration requires higher, not lower, environmental protection standards. Higher protection need not necessarily be more burdensome. We propose reforms to environmental risk assessment (see the box) that would make better use of existing data and facilitate timely assessments through specialized evaluating bodies, more easily interpretable statistical outcomes, and harmonized criteria for study appraisal. Although some proposed reforms require initial efforts, they would substantially strengthen environmental protection while reducing regulatory burden in the midterm. Strengthening preapproval substance assessments would prevent harmful pesticides from reaching

Pesticide regulation in the EU at a crossroads

Circled numbers indicate key features of the Omnibus-proposed changes and the authors' proposed safer alternative, which could exacerbate (●) or mitigate (○) shortcomings under the current approach to risk assessment.

Omnibus package

PREMARKET ASSESSMENT

❶ Expands EU-wide authorizations without limiting choice of evaluating Member State
❷ Weakens knowledge consideration in product evaluations

POSTMARKET LAUNCH

❸ Waives record-keeping for biocontrol products
❹ No reassessment of most active substances
❺ Grants grace periods (the time nonrenewed pesticides remain in use) to higher-risk pesticides and for twice as long

IMPACTS

- Increases risks for the environment and human health
- Reduces incentives to develop safer pest control
- Reduces trust in regulatory processes
- Undermines EU and international environmental commitments

Safer alternative

PREMARKET ASSESSMENT

① Improve coverage of vulnerable taxa
② Develop and test against protection goals
③ Increase transparency of regulatory studies
④ EU assigns evaluation responsibilities for products among Member States

POSTMARKET LAUNCH

⑤ Systematic postauthorization monitoring
⑥ Spatially explicit pesticide use and monitoring data made available
⑦ Feedback mechanisms between monitoring and risk assessment

IMPACTS

- Improves detection of harmful substances before and after market entry
- Enables evidence-based, adaptive regulation
- Reinforces precautionary principle and transparency rules
- Supports environmental commitments

Shortcomings of the current approach

PREMARKET ASSESSMENT

- Amphibians, reptiles, and bats are not represented ①
- Underpowered studies overlook detrimental effects ②
- Mixture and cumulative effects ignored ⑤⑥⑦
- Environmental fate insufficiently predicted ⑤⑥⑦
- Applicants can choose an evaluating Member State with lower standards in plant protection product evaluations ❶④

POSTMARKET LAUNCH

- Slow identification and phase-out of pesticides eliciting unacceptable harm ❷❸❹❺⑤⑥⑦

the market and reduce the need for postapproval restrictions and the search for alternatives (*7*). Effective feedback mechanisms from monitoring would enable prioritization of substances for targeted reassessments. Specifically, we propose the following reforms as a blueprint for more effective and efficient environmental risk assessment.

Address backlog in regulatory assessments without abandoning safeguards

Capacity constraints among evaluating Member States and the submission of incomplete renewal applications have driven delays (*2*, *8*). To clear this backlog within 3 years, EFSA estimates that hiring 50 additional staff and €15 million annually would suffice (*8*)—a modest investment relative to the hundreds of millions the chemical industry spends for bringing a single active substance to market and to the health and environmental costs caused by substances that lead to undetected unacceptable harm. To prevent delays, incomplete applications could be rejected and fees raised to fully cover assessment costs, ensuring that adequate resources are available (*2*).

Improve coverage of potentially vulnerable taxonomic groups

Efforts to develop protocols for currently underrepresented groups should continue, prioritizing test species that are expected to be particularly vulnerable on the basis of traits related to exposure, sensitivity, and recovery.

Develop and test against protection goals across all test species

To ensure that conclusions of pesticide safety are statistically reliable, equivalence testing, which was recently proposed by EFSA in higher-tier studies for bees, should become mandatory across all species. Unlike conventional significance testing, it does not test whether effects exist but whether they are below protection goal thresholds. This shifts the burden of proof to pesticide manufacturers and incentivizes sufficiently powered studies. It also ensures efficient resource allocation, as demonstrating safety requires a higher sample size for a substance that exerts small effects than one without effects. Implementation across taxa requires quantifiable protection goal thresholds for species beyond honey bees and formal recognition by Member States.

Increase transparency of regulatory studies

To increase trust in regulatory processes and enable efficient targeted verification by independent scientists, manufacturers' studies on the risks of a substance should be published open access on a dedicated EU server. Preregistration of study protocols and statistical analysis plans on the same server would prevent selective analysis, choices, and reporting. In the longer term, trust in the approval process could further be strengthened by having independent EU-appointed institutes conduct regulatory studies, with an EU body channeling industry funding to prevent direct financial dependency between evaluators and industry while avoiding a shift of regulatory costs to taxpayers.

Reform the assignment of evaluating Member States in plant protection product evaluations

The EU should either appoint the evaluating Member State or divide responsibilities among Member States by assessment area, enabling specialization. This would address the cherry-picking of evaluating Member States by applicants for non–use-related reasons and correct the unfair workload distribution among Member States, which has contributed to delays in regulatory assessments, as the Commission itself acknowledged (*2*). By removing applicants' ability to choose the evaluating Member State, the reform would also enable a broader use of the one-zone system than proposed by the Omnibus, cutting administrative burdens without risking lowering assessment standards. By contrast, the Omnibus suggestion to force applicants to market products in the countries where they seek authorization creates regulatory burdens for policing compliance without removing the incentive to seek authorization where assessment practices are the least stringent.

Reinforce the integration of independent science into regulatory assessments

Independent studies should be evaluated using mandatory, harmonized strength-of-evidence protocols to assess scientific reliability, reporting transparency, and ecological relevance. EFSA's proposed critical appraisal tools for ecotoxicology studies and guidance from the Organisation for Economic Co-operation and Development on the generation, reporting, and use of research data provide a useful foundation but should be codified into obligatory protocols. This would ensure that peer-reviewed academic and industry-funded studies are weighted consistently and transparently, while improving the efficiency of individual study appraisals.

Systematic postauthorization monitoring of pesticide use, residues, and impacts

The real world is too complex for premarket assessments to capture all possible pesticide combinations and exposure scenarios. Ignoring them altogether can, however, have severe consequences. Systematic monitoring of pesticide use, residues, and impacts is therefore crucial, and some foundations are in place: Nature Restoration Regulation now mandates pollinator population monitoring, and Implementing Regulation (EU) 2023/564 requires farmers to keep electronic, machine-readable records of pesticide applications and to make them available upon request to competent authorities. However, these data are not yet systematically accessible to regulators or the scientific community. Existing monitoring schemes should be complemented with additional residue screenings. Pesticide use, residue, pollinator and other available population data should be made available for regulatory and scientific assessment—ideally at the field level. This would enable validation of premarket exposure models, improve understanding of environmental fate and exposure pathways, support detection of effects on nontarget organisms, and inform landscape-level pesticide load thresholds akin to those used for river and groundwater contaminants under the EU's Water Framework Directive. If data protection rights prevent the systematic release of high-resolution pesticide use data, aggregated access sufficient for exposure model validation should nonetheless be ensured for regulators.

Establish feedback loops between postauthorization monitoring and risk assessment

Such feedback loops are a defining feature of systems-based environmental risk assessment now advocated by EU regulators and modelers alike (*9*, *10*). Operational components already exist: The ApisRAM honey bee colony model, commissioned by EFSA, runs on the ALMaSS landscape simulation platform at meter-scale resolution and links pesticide exposure, floral resources, weather, and management to colony-level outcomes. Realistic landscape-level exposure can be integrated with effect models to assess whether specific protection goals are met. This can support both pre- and postauthorization evaluation and provide a mechanism for triggering targeted reassessment when monitoring shows protection goals are no longer met. Additionally, procedures for analyses of pesticide use and population data that trigger additional residue analyses and/or targeted analyses of mixture effects should be established.

Regulating pesticide approvals is only one pillar of risk reduction. Across Europe, there are many examples of governance and policy solutions that reduce farmers' reliance on pesticides while maintaining livelihoods and food security (*11*). Economic disincentives comprise risk-based pesticide taxation, whereas incentives include financial support for integrative pest management, agroecological practices, targeted subsidies, and independent advisory services (*11*). Market-based instruments (e.g., supply chain standards, public procurement criteria, and labeling schemes that reward pesticide reduction) can further reinforce these incentives by reshaping value-chain expectations and demand. These could be grounded in spatially explicit real-world data on pesticide use, residues, and impacts, provided these data are systematically collected, transparently governed, and accessible for independent scientific assessment. Additionally, pesticide risks to biodiversity can be reduced through incentivizing land management that provides compensatory habitats serving as shelter and food source (*12*).

The Omnibus risks locking the EU into outdated, underprotective assessments while weakening accountability and scientific scrutiny. A reoriented framework grounded in clearly defined protection goals, robust premarket testing, systematic postauthorization monitoring, and transparent integration of independent science could improve protection of humans and nature while limiting administrative workload. □

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