

Dear European Commission President Von der Leyen:

We, members of the scientific and medical community, are writing to underscore the **urgent need to better protect the environment, biodiversity and citizens against exposure to harmful pesticides**. We are increasingly concerned about shortcomings in the regulatory framework that is intended to ensure the safe approval of pesticide active substances and authorisation of plant protection products (**Regulation (EC) 1107/2009**). The draft of the forthcoming Omnibus Simplification Package includes alarming changes to Regulation (EC) 1107/2009, which would **drastically undermine the EU's ability to respond to risks that only become evident once approved pesticides are in wide use** and create **loopholes that keep harmful pesticides in use**, even the ones with well-documented and recognised risks.

We call for European policymakers to reject the harmful revisions proposed in a draft of the Omnibus Bill and we offer recommendations for strengthening the risk assessment and management under the EU regulatory framework. A protective framework must:

- **Ensure pre-market risk assessment** of active substances and marketed pesticide products, including biocontrol, is based on the **latest¹ independent scientific and technical knowledge and robust, realistic assessment**. Testing should include sensitive indicators and real-world scenarios, such as improved assessment of the environmental and human health impacts of mixtures and those resulting from long-term and chronic exposures.
- **Maintain periodic and ad-hoc review** of active substances and pesticide products, including biocontrol, to **quickly respond to emerging risks that only emerge when pesticides are in wide use or new science becomes available²**. Stronger mechanisms for continuous reassessment should include data and monitoring systems to detect and respond to patterns of risk.

In light of these essential prerequisites, we discuss key shortcomings in the Omnibus proposal and recommendations for improvement:

1) Mandatory periodic review of approved pesticide active substances (Art. 20) is the principal mechanism for ensuring harmful effects emerging in real-world use leads to restriction and removal from the market.

The Omnibus proposes the removal of mandatory ten-year review of active substances approved at the EU level. **The essential safeguard of periodic reviews must not be removed**. Pesticide active substances are approved with pre-market tests and modelled scenarios that cannot capture the complexity of real-world pesticide use. Both periodic (Art.

20) and ad hoc (Art. 21) review allows regulators to incorporate new scientific insights which often emerge only after a pesticide is widely used and/or when academia has had the opportunity to evaluate these substances as well. Numerous examples show that pesticides can initially appear safer or less persistent during registration, then later prove harmful to ecosystems and human health under real use³. In fact, the link between systematic post-market monitoring and regulatory reassessment should be further strengthened, not removed: currently, real-world data from the monitoring of soil, surface water, groundwater and humans rarely trigger the re-evaluation of existing authorisations⁴.

Further Recommendations: improve and harmonise monitoring program, data systems, and pesticide use registries to detect and act on emerging risks. Biocontrol and biopesticides must be included in monitoring and pesticide use registries, as well (See Annex).

2) Pesticides demonstrated to be harmful should be quickly removed from the market and use, linking the latest scientific evidence to the protection of humans and the environment.

The Omnibus proposes a grace period of 36 months for continued use of active substances deemed too toxic for use, opening farmers, consumers and the environment to potential harm when there is clear knowledge of unacceptable risks. **The grace period allowing for use of banned harmful pesticides should be reduced or eliminated, not increased.**

Further Recommendations: withdraw the approval of wider classes of pesticides already proven or strongly indicated to be particularly harmful (See Annex).

3) At the registration of plant protection products (PPPs), the latest available science must be considered by member state evaluators, ensuring the highest possible level of protection.

Individual pesticide active substances are first approved at the EU level, while the products (PPPs) containing these substances are later (re)approved by Member States. The Omnibus would remove the requirement for the inclusion of the latest available evidence on active substance hazards to be included when the products containing those are authorised, inconsistent with a recent CJEU ruling⁵. Without this requirement, PPP applicants can “copy-paste” conclusions from old dossiers as evidence, even if current scientific research undermines those older findings. **This loophole can cut out the best available knowledge of harm from the risk assessment process and should not be included.**

Recommendation: Create stronger inclusion criteria for independent scientific assessments during risk assessment, as current practice prioritises industry studies⁶ (See Annex).

4) Pre-market assessment of pesticides should include more realistic and sensitive detection of hazards and risks, preventing more harmful pesticides from reaching the market.

While the Omnibus proposal does not specifically mention pre-market risk assessment evaluation requirements, we nonetheless draw attention to the opportunity for substantial improvement. In the current framework, pre-market assessments largely focus on individual active substances and controlled scenarios, overlooking the assessment of mixtures⁷ that are widespread in the environment⁸ and can be more harmful than their individual components⁹. The health impacts on particularly sensitive groups is still underdeveloped. Toxicity assessment is often based on only standard laboratory tests, which can fail to capture real world effects¹⁰. Exposure assessments are often based on simplistic routes of human uptake¹¹, failing to account for important knowledge gaps¹² in exposure science.

***Recommendations:** Expand pre-market evaluation to include better assessment of mixture effects, more sensitive toxicology tests, more screening for development and neurotoxicity, and more thorough assessment of human non-dietary uptake of pesticides (See Annex).*

Independent scientific research has documented a range of environmental and health impacts linked to many pesticides, underscoring the need for precaution. Mixtures of residues are frequently found in soils, air, water, vegetation, crops, food, wildlife, and indoor environments¹³. Pesticides are a recognised driver of biodiversity decline, with evidence of direct and indirect effects on insects¹⁴, birds¹⁵, soil organisms¹⁶, amphibians, fish and mammals¹⁷. Epidemiological and toxicological studies associate exposure to certain pesticides with increased risks of chronic health conditions¹⁸, including specific cancers¹⁹, neurodegenerative diseases (Alzheimer's, Parkinson's)²⁰, neurodevelopmental disorders²¹, reproductive and fertility impacts²², and immune or metabolic effects, including on the gut microbiome²³. Risks may be higher for vulnerable groups such as pregnant women, infants and children, farmers, and residents of intensively farmed areas²⁴.

It is possible to achieve efficient and resilient cropping systems, while also keeping harmful pesticides off the market. Farmers across Europe are already practicing robust, ecosystem-based agriculture that phases out pesticides or uses them only exceptionally. Policymakers can help scale these approaches by **ensuring implementation of IPM**, strengthening **CAP incentives** for agroecological practices and supporting **independent advisory services**.

Taken together, the evidence is clear: many pesticides cause harm to human health and the environment, and much of this becomes **visible only after wide use**. Pre-market testing must be made more **robust, sensitive, and relevant for realistic use**, complemented by **regular science-based reviews to detect real-world risks**, while supportive policies help farmers adopt resilient, low-pesticide practices.

We respectfully ask you to protect biodiversity, ecosystems and human health through a strong risk assessment framework, rejecting the listed draft provisions in the Omnibus and considering further strengthening protections in Regulation (EC) No 1107/2009. We are at your disposal for further exchange of information.

Yours sincerely,

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Annex: key recommendations for strengthening pesticide risk assessment

#1) Strengthen the feedback of the best and latest available science to the (re)authorisation or withdrawal of all active substances and pesticide products. This includes independent and current science, emerging topics such as neurotoxicity, monitoring results, and population-wide health outcomes.

Context: Risks from long-term and chronic pesticide exposure are difficult to detect in pre-market testing and often become evident only once a pesticide is in widespread use²⁵. The pesticide assessment system systematically privileges industry studies while sidelining independent, peer-reviewed science. By treating Good Laboratory Practice (GLP) as the primary marker of credibility—despite GLP being a documentation standard rather than a measure of scientific validity—regulators routinely discount newer, independent academic research, narrowing the scientific base of assessments and obscuring emerging risks.²⁶

#2) Better assess the acute and chronic toxicity of realistic pesticide mixtures encountered by humans and exposed wildlife, instead of just individual substances, by testing recommended tank mixes, spray series and common mixtures found in the environment.

Context: Pesticides are currently assessed on a substance-by-substance basis, but mixtures of pesticides are widespread in the environment in soils, air, water, vegetation, crops, food, animals, humans and in indoor dust.²⁷ Insects and other organisms are chronically exposed year-round to landscape-scale pesticide mixtures, while the regulatory risk assessment mainly accounts for acute exposures for a single spraying event²⁸. Realistic mixtures of pesticides have been found to adversely affect soil and aquatic organisms, even when levels of individual substances were considered safe through regulatory assessment²⁹. Even planned mixtures such as recommended tank mixes are not consistently evaluated for safety³⁰, and application sequences are not addressed at all³¹. Models used in current regulations do not reliably predict how pesticides will travel and degrade in the environment, with a recent study showing poor correlation between predicted environmental concentrations in soil (PEC) and concentrations measured in the environment (MEC)³².

#3) Include more realistic and sensitive toxicity tests in pre-market evaluations. All pesticides need to be tested for neurotoxicity, including developmental neurotoxicity, target toxicity for more human organs and ecotoxicological impacts on more sensitive species, rather than only standard test organisms. More standardised mesocosm and ecosystem tests could add realism to the environmental assessment.

Context: Required pre-market toxicity testing on limited standard tests on human and ecological toxicology, which are often not sufficiently sensitive to detect pesticide toxicity in the real world.³³ In laboratory tests using alternative sensitive species, sensitive ecological indicators, and new human organ tests, pesticides were shown to have detrimental effects not detected in regulatory assessment.³⁴

#4) Require more thorough assessments of human exposure to pesticides, better accounting for pesticides humans encounter in the environment or near fields. We urgently need to include the long-term health effects of low-dose exposure to pesticide mixtures, especially during sensitive early life stages.

Context: The current regulation focuses mainly on human pesticide exposure through food intake, whereas pesticides in the environment can also significantly contribute to overall human pesticide exposure, e.g., through inhalation, dermal contact or ingestion³⁵. Farmers and their neighbors can be exposed to spraying from multiple farms in the same vicinity.³⁶

#5) Introduce Human Biomonitoring Programs to support detection of human exposures for all sources and routes of uptake. When active substances are approved, **Biological Guidance Values (BGV)** should be set, which define safe levels of active substance in human samples (e.g., blood, urine), supporting human biomonitoring.

Context: human biomonitoring directly measures internal exposure by detecting pesticide metabolites in biological samples (urine, blood, hair), and has successfully detected risks from a range of chemical exposures, and a recent human biomonitoring study found that 84% of sampled children and adults carried residues of two or more pesticides.³⁷ The Netherlands has endorsed the use of BGVs to support human biomonitoring³⁸, while the EU pesticide regulation only recognises acceptable dietary intake (ADI) as a measure of human exposure.

#6) Include stronger safety margins for allowable pesticide exposures to account for critical missing data and exposure to mixtures in food and the environment.

Context: Scientific knowledge gaps and critical missing data undermine the certainty of pre-market risk assessment, especially for effects on children, pregnancy and fertility. There is critical missing knowledge in how pesticides are processed in the human body³⁹ and in emerging topics like gut microbiome research. Allowable exposure limits can be lowered where data is missing.

#7) Require mandatory digital registration of all pesticides applied on fields, including biocontrol products and agents, so that spatial pesticide usage data at high resolution per crop type are readily available and allow for systematic **detection of risk and exposure patterns**.

Context: Data availability of pesticide use is absolutely key for research, exposure and impact assessments, as well as for management and policy decisions, but only a few Member States have complete digital registries of use. In addition to monitoring the use of synthetic pesticides, possible risks for biocontrol products, such as insects and viruses, must also be closely followed through digital registrations.

#8) Withdraw the approval for particularly harmful pesticides, such as candidates for substitution, PFAS pesticides, co-formulants and pesticides degrading into particularly harmful metabolites, as well as other pesticides proven or strongly indicated to be particularly harmful (carcinogens, mutagens, toxic for reproduction, endocrine disruptors, neurotoxic, persistent, bioaccumulative and toxic (PBT), very persistent, and very mobile (vPvM), very persistent and very bioaccumulative (vPvB). There **should not be a grace period for use after withdrawal**, reflecting appropriate precaution for environmental and human health.

Endnotes

1. CJEU Case C-308/22 (2024). [Pesticide Action Network Europe \(PAN Europe\) v College voor de toelating van gewasbeschermingsmiddelen en biociden](#)
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