

Comments on the call for evidence for simplification of the food and feed safety legislation

PAN Europe

14 October 2025

Pesticide Action Network Europe (PAN Europe) welcomes the opportunity to contribute to the call for evidence for the "Food and feed safety - simplification omnibus".

PAN Europe is a science-based organisation composed of toxicologists, legal experts and policy officers. We bring together more than 50 consumer, public health and environmental organisations, trades unions, women's groups and farmer associations from across Europe. Together, we work to eliminate the dependency on pesticides and to replace their use with ecologically sound and socially just alternatives. We have extensive expertise in European and national pesticide legislation and its implementation. Accordingly, our fact- and science-based contribution will address the related aspects of the initiative (Pesticides, Maximum Residue Levels (MRLs) and biocides).

First, we wish to remind the Commission of the broad public demand for stricter regulation to phase out synthetic pesticides, as well as support for farmers who have already stopped or are in transition to significantly reduce their use. This demand has been consistently expressed across the EU in recent years¹ through consultations, barometers, opinion polls, and two successful European Citizens' initiatives. The European Commission's credibility and citizens' trust towards the EU depend on respecting the outcomes of its own participatory processes, including in the context of this initiative.

We will structure our reply by addressing, point by point, the list of "problems that the initiative aims to tackle" compiled by the European Commission for pesticides and MRLs.

1

¹ Citizens' Demands for Pesticide Reduction in Europe

Phase out of harmful pesticides

The call for evidence notes that "Farmers face a shrinking toolbox as older products lose authorisation". However, it is important to emphasise that there are currently 422 active substances approved in the EU, providing EU farmers with a substantial range of chemical and non-chemical substances for crop protection. Out of these substances, the synthetic and other most hazardous ones should be used as a very last resort, in line with the mandatory integrated pest management principles, as is explained below.

The Pesticide Regulation 1107/2009 is a cornerstone of EU legislation, designed to ensure a high level of protection from pesticides. It establishes strict approval criteria to prevent the approval of substances that are inherently toxic, as synthetic pesticides are designed to kill or inhibit insects, fungi, and weeds. As a result, over the past decades, numerous active substances have been banned due to their proven harmful effects on humans, animals, and ecosystems. We therefore encourage the European Commission to present the banning of pesticide substances as a positive move in the transition towards sustainable farming, not as something negative for farmers. Unfortunately, many harmful pesticides are still widely used.

As <u>documented</u> by the EU-funded SPRINT project, European citizens are continuously exposed to a cocktail of hazardous pesticide residues through air, water, soil, house dust, and food, with impacts extending far beyond agricultural areas². <u>Biomonitoring data</u> indicate the presence of these chemicals, often in combination, in both adults and children³. **Chronic exposure to pesticides has been linked to a <u>wide range of diseases</u>, including multiple types of cancer, respiratory illnesses, reproductive disorders, neurodegenerative diseases, and developmental delays in children⁴. Farmers, agricultural workers, and rural communities face heightened risks, with evidence pointing to increased incidences of blood cancers, prostate cancer, and Parkinson's disease⁵. Children, whose bodies and neurological systems are still developing**

_

² Silva et al. (2023). Pesticide residues with hazard classifications relevant to non-target species including humans are omnipresent in the environment and farmer residences, Knuth et al. (2024). Pesticide Residues in Organic and Conventional Agricultural Soils across Europe: Measured and Predicted Concentrations, EEA (2024). Europe's state of water 2024: the need for improved water resilience, PAN Europe (2025). Ban PFAS pesticides and TFA, PAN Europe (2025). Increase of pesticide cocktails in European food: New EFSA Report confirms widespread exposure, The return of EU-banned pesticides: dangerous residues found in imported food, Navarro et al. (2023). Occurrence of pesticide residues in indoor dust of farmworker households across Europe and Argentina

Human biomonitoring: https://www.hbm4eu.eu/ - substance report, Huber et al. (2022). A large scale multi-laboratory suspect screening of pesticide metabolites in human biomonitoring: from tentative annotations to verified occurrences, Ottenbros et al. (2023). Assessment of exposure to pesticide mixtures in five European countries by a harmonised urinary suspect screening approach

Inserm (2021). Collective Expert Review on the Health Effects of Pesticides, EEA, 2023: How pesticides impact human health and ecosystems in Europe, Silva et al. (2023). Pesticide residues with hazard classifications relevant to non-target species including humans are omnipresent in the environment and farmer residences, Alaoui (2024). Identifying pesticides of high concern for ecosystem, plant, animal, and human health: A comprehensive field study across Europe and Argentina, Panzachi et al. (2025). Carcinogenic effects of long-term exposure from prenatal life to glyphosate and glyphosate-based herbicides in Sprague—Dawley rats, EU citizens are not protected against neurotoxic effects of pesticides, Pesticides play role in Parkinson's explosion, says Dutch expert, Bloem and Boonstra, (2023). The inadequacy of current pesticide regulations for protecting brain health: the case of glyphosate and Parkinson's disease, Matsuzaki et al. (2023). Pesticide exposure and the microbiota-gut-brain axis, Diwan et al. (2023). Impact of Pesticide Residues on the Gut-Microbiota-Blood—Brain Barrier Axis: A Narrative Review, Gama et al. (2022). Chronic Effects of Dietary Pesticides on the Gut Microbiome and Neurodevelopment, PAN Europe (2025). The impact of pesticides on citizens' health

⁵ Kab et al. (2017). Agricultural activities and the incidence of Parkinson's disease in the general French population

prenatally and during early postnatal stages, have been shown to develop cognitive disorders as a result of early-life exposure to pesticides⁶.

The environmental impacts are even more compelling. Pesticides contaminate terrestrial and aquatic ecosystems, threatening countless species and their habitats. The Commission-supported <u>INSIGNIA-EU</u> preparatory action, which used honeybees environmental microsamplers due to their broad flying range and the bee relevance to food security, demonstrated the widespread presence of pesticide residues, including some illegal substances. Insect and bird populations are plummeting at alarming rates, with pesticides as a major driver⁷. Pesticide drift, for example, reduces wild plant diversity by over 50% within 500 metres of treated fields, drastically limiting resources for pollinators. This widespread pesticide pollution and collapse of biodiversity undermines critical ecosystem services, such as pollination, pest control, soil health and water quality, which are essential for citizens' and societal well-being, including for sustainable agriculture and food security. As underlined by scientists, the biggest risks to food security stem from climate change and the loss of biodiversity and ecosystem services, such as pollination and pest control.

Unfortunately, **the ban of harmful substances is often long overdue**. In recent years, for example, some harmful substances have been banned following their identification as endocrine-disrupting (ED) pesticides. Regulation 1107/2009 is meant to prohibit the approval of ED pesticides since 2011, because of their serious, irreversible impacts on health and the environment. Nevertheless, the scientific criteria necessary to identify such substances were only established in 2018, finally enabling regulators to begin their assessment. This process was further prolonged by the provision of allowing industry up to 30 additional months to submit data already required under the data requirements Regulation (283/2013) since 2013. Subsequent delays in regulatory decision-making resulted in the first ED pesticides being banned only in 2023, twelve years after the legal requirement entered into force. These delays have had concrete implications: ED pesticides were prolonged on the market well beyond their initial approval periods, thereby continuing to expose citizens and the environment to harmful

Doğanlar et al. (2018). <u>Nonoccupational Exposure of Agricultural Area Residents to Pesticides: Pesticide</u>
Accumulation and Evaluation of Genotoxicity

Figueiredo et al. (2019). Spatio-temporal variation of outdoor and indoor pesticide air concentrations in homes near agricultural fields

⁶ Taiba et al. (2025). Exploring the Joint Association Between Agrichemical Mixtures and Pediatric Cancer, Parrón-Carrillo et al. (2024). Environmental Exposure to Pesticides and the Risk of Child Neurodevelopmental Disorders, PAN Europe (2023). Science calls for protection of children's health from long-term impacts of pesticides, Bretveld et al. (2006). Pesticide exposure: the hormonal function of the female reproductive system disrupted?, Farr et al. (2004). Pesticide use and menstrual cycle characteristics among premenopausal women in the Agricultural Health Study

⁷ Hallmann et al. (2017). More than 75 percent decline over 27 years in total flying insect biomass in protected areas Seibold et al. (2019). Arthropod decline in grasslands and forests is associated with landscape-level drivers, Brühl et al. (2021). Direct pesticide exposure of insects in nature conservation areas in Germany, Gunstone et al. (2021). Pesticides and Soil Invertebrates: A Hazard Assessment, Rigal et al. (2023). Farmland practices are driving bird population decline across Europe, Beaumelle et al. (2023). Pesticide effects on soil fauna communities - A meta-analysis, EEA, 2023: How pesticides impact human health and ecosystems in Europe, Brühl et al. (2024). Widespread contamination of soils and vegetation with current use pesticide residues along altitudinal gradients in a European Alpine valley, Wan et al. (2025). Pesticides have negative effects on non-target organisms, Honert, Mauser, Jäger, & Brühl (2025). Exposure of insects to current use pesticide residues in soil and vegetation along spatial and temporal distribution in agricultural sites, Mauser et al. (2025). Current-use pesticides in vegetation, topsoil and water reveal contaminated landscapes of the Upper Rhine Valley, Germany

substances. Furthermore, all banned ED pesticides were granted extended grace periods ranging from nine to eighteen months, further postponing the withdrawal of these hazardous products.

Table: Overview of 10 non-approved/non-renewed ED-active substances

Substance Name	Extensions of approval	Date of ED identification	Date of adoption of ban	Grace Period
Clofentezine	9 years 01/01/2009-11/11/ 2023 (initially 31/12/2012)	July 2021	November 2023 (Regulation EU 2023/2456)	12 months
Benthiavalicarb	5 ½ years 01/08/2008-13/12/ 2023 (initially 31/07/2018)	August 2021	November 2023 (Regulation EU 2023/2657)	12 months
Triflusulfuron- methyl	4 years 01/01/2012-20/11/ 2023 (initially 31/12/2019)	March 2022	November 2023 (Regulation EU 2023/2513)	9 months
Metiram	8 ½ years 01/07/2006-31/01/ 2024 (initially 30/06/2016)	March 2023	November 2023 (Regulation EU 2023/2455)	12 months
Asulam sodium	Not relevant	October 201	February 2024 (Regulation EU 2024/425)	Not relevant
Dimethomorph	8 years 01/10/2007-15/02/ 2025 (initially September 2017)	June 2023 (also classified R1B since September 2019)	April 2024 (Regulation EU 2024/1207)	12 months
Mepanipyrim	10 ½ years 01/10/2004-15/03/ 2025 (initially 30/06/2014)	August 2023	April 2024 (Regulation EU 2024/1217)	12 months

Acibenzolar-S-Not relevant July 2021 June 2024 12 months (Regulation EU methyl (Article 21) 2024/1696) Metribuzin 12 months 8 ½ years August 2023 October 2024 (Regulation EU 01/10/2007-15/02/ 2024/2806) 2025 (initially 30/09/2017) Flufenacet 11 ½ years September May 2025 18 months (Regulation EU 2024 01/01/2004-10/06/ 2025/910) 2025 (initially 31/12/2013)

It should also be noted that the 20 active substances identified as ED by EFSA represent **only a small fraction**, **i.e.**, **14%**, **of the 142 that have undergone ED assessment in recent years**⁸. For most substances, EFSA was either unable to draw a conclusion for humans and/or non-target organisms due to insufficient data, or concluded they did not meet ED criteria. Alarmingly, substances for which a scientific conclusion could not be reached remained approved and on the market. For 18 additional active substances, further data are currently being requested from the industry, and the assessment is still ongoing.

The ban of ED pesticides is stalled. Four identified endocrine disruptors for humans by the European Food Safety Authority (EFSA) have been under discussion between Member States and the European Commission since the beginning of the year (bruprofezin, cyprodinil, fludioxonil, and fenoxaprop-P-ethyl). This is an unacceptable delay, particularly as these concern substances which fulfil the criteria to be considered particularly hazardous, and therefore should be banned without further assessment (referred to as cut-off criteria) according to Regulation 1107/2009.

The same unacceptable delays are observed for other highly hazardous substances, classified as toxic for reproduction category 1B (Repr. 1B) under Regulation 1272/2008. Currently, **three substances classified as toxic for reproduction category 1B** are still approved in the EU, in contradiction to the provisions of Regulation 1107/2009. Other reprotoxic 1B substances, such as dimethomorph⁹, were banned years after their harmonised classification occurred.

⁸Please refer to EFSA overview table:

²⁰²⁵⁻⁰⁶⁻²⁰⁻ed-report-overview-endocrine-disrupting-assessment-pesticide-active-substances.xlsx

⁹ Dimethomorph was classified as toxic for reproduction category 1B in an ECHA opinion of September 2019. A Regulation was adopted to ban it in April 2024.

Table: Overview of Repr. 1B active substances

Substance name	Harmonised classification	Extensions of approval
Flurochloridone	November 2018	01/06/2011-15/03/2026 (initially 21/05/2021)
Halosulfuron-methyl	September 2017	01/10/2013-31/03/2025 (initially 30/09/2023)
Quinoline-8-ol (previously 8-hydroxyquinoline)	September 2019	01/01/2012-31/12/2024 (initially 31/12/2021). Renewed in June 2025 (negligible exposure condition)

There are more particularly problematic active substances that remain on the market today.

- 45 active substances are approved as candidates for substitution, i.e., are considered 'more hazardous' pesticides because they meet one of the criteria laid down under point 4 of Annex II of Regulation 1107/2009. This represents 10% of the currently approved active substances.
- 32 PFAS active substances are currently approved in the EU. Due to their chemical structure (C-CF3), all are identified or are potential precursors of trifluoroacetic acid (TFA), releasing it into the environment upon degradation. TFA is an exceptionally persistent and very mobile ultra-short PFAS proposed for classification as toxic for reproduction category 1B under Regulation 1272/2008, because of its reprotoxic and teratogenic properties. As revealed in our recent report of 29 September 2025, TFA induces adverse effects even at low doses and across different species, including eye and skeletal malformations, thyroid hormone disruption, liver damage, effects on the immune system and reduced sperm quality.

Other particularly problematic categories of substances are still approved in the EU, including active substances with developmental neurotoxicity properties, affecting children's brain health and azole substances, which are toxic themselves and contribute to antimicrobial resistance.

Extensive shortcomings in current pesticide risk assessment and approval

The implementation of Regulation 1107/2009 urgently needs to be strengthened. Current pesticide risk assessment continues to suffer from severe shortcomings in its implementation, undermining the Regulation's core objective of protecting human health and the environment

from harmful pesticide effects. These weaknesses were already thoroughly documented by the European Parliament's Special Committee (PEST Committee) in 2019, following several months of in-depth investigations. The Committee concluded that the current system for pesticide authorisations is failing to achieve its purpose and called for a much stronger implementation of the EU's pesticide legislation. Despite the Committee's 116 recommendations demanding greater independence, objectivity, transparency, and stronger reliance on science, very few have been implemented. As a result, the high level of protection required by EU law remains to be achieved. Likewise, the key outcomes of the EU SPRINT project highlight that pesticide risk assessment is in clear need for improvement, and that present risk assessment methods likely underestimate the risks pesticides pose to human and environmental health.

The failure to remove endocrine-disrupting (ED), reprotoxic and other harmful pesticides from the market exemplifies these systemic shortcomings. Another glaring gap concerns neurotoxicity, which is still not adequately assessed in pesticide risk evaluations, despite growing expert warnings of a "Parkinson's pandemic" linked to pesticide exposure 10. Moreover, different exposure routes (e.g. respiratory and dermal routes) are not, or very poorly, taken into account in risk assessment. Last, although required by law, the cumulative and synergistic effects of pesticides, the so-called "cocktail effects", are still not taken into account in risk assessment.

Environmental risk assessments fare no better. The impact of pesticides on ecosystems, biodiversity, and ecological functioning remains grossly underestimated, in clear violation of the legal requirement that pesticides must not adversely affect the environment (they must have no unacceptable effects). For example, current risk assessments fail to evaluate critical impacts on amphibians and guidelines remain to be established, despite their sensitivity to chemical pollution and their role as key indicators of ecosystem health. Moreover, the EU guideline used by EFSA and national authorities to assess effects on so-called "non-target" arthropods has, under pressure from the agrochemical industry, effectively become a license to continue using substances that decimate insects, spiders, beetles, butterflies, and other vital arthropods.

Scientific evidence shows that mixtures of pesticide residues now cause <u>widespread</u>, <u>landscape-scale pollution</u>, reaching even remote ecosystems and conservation areas. Yet, current risk assessment procedures fail to account for the chronic, cumulative risks of these mixtures. Experts are unequivocal: without decisive action to reduce pesticide use and enforce the law, Europe will face further and irreversible biodiversity loss¹¹.

_

¹⁰ EU citizens are not protected against neurotoxic effects of pesticides, Pesticides play role in Parkinson's explosion, says Dutch expert, Bloem and Boonstra. 2023. The inadequacy of current pesticide regulations for protecting brain health: the case of glyphosate and Parkinson's disease, Matsuzaki et al. 2023. Pesticide exposure and the microbiota-gut-brain axis, Diwan et al. 2023. Impact of Pesticide Residues on the Gut-Microbiota-Blood–Brain Barrier Axis: A Narrative Review, Gama et al. 2022. Chronic Effects of Dietary Pesticides on the Gut Microbiome and Neurodevelopment

¹¹ We need a food system transformation - In the face of the Russia-Ukraine war, now more than ever, March 2022, Scientists call for ambitious Sustainable Use of Pesticides Regulation. December 2022, Scientists support the EU's Green Deal and reject the unjustified argumentation against the Sustainable Use Regulation and the Nature Restoration Law, Brühl et al. (2024). Widespread contamination of soils and vegetation with current use pesticide residues along altitudinal gradients in a European Alpine valley, Honert et al. (2025). Exposure of insects to current use pesticide residues in soil and vegetation along spatial and temporal distribution in agricultural sites

Moreover, the lack of robust indicators for pesticide use and risk, as well as the lack of digital data on pesticide use, pose a major barrier to assessing pesticide trends. It is key to replace the Harmonised Risk Indicator (HRI-1), which is scientifically unfounded and provides <u>misleading</u>, <u>incorrect information</u> about the trends in pesticide use and risk. Therefore, <u>a complaint</u> to the European Ombudsman was submitted. In addition, <u>Electronic registration of pesticide use</u> is key, long overdue, and should be implemented without delay, in line with Regulations 1107/2009, 2022/2379 and 2023/564.

Only through full implementation and rigorous enforcement of existing legislation can the EU truly protect people, wildlife, and ecosystems from the escalating harms of pesticide pollution.

Banning harmful pesticides does not endanger EU farmers' yields or profitability, contrary to certain claims. Eurostat data show that EU crop yields have remained stable from 2013 to 2023 despite increasing bans on harmful pesticides. As indicated earlier, the biggest risks to food security stem from climate change and the loss of biodiversity and ecosystem services, such as pollination and pest control. Banning harmful substances will exactly further foster the uptake of available ecologically sound alternatives. Integrated Pest Management (IPM) enables the phase-out of harmful pesticides while maintaining yields and, good, or even increasing, profits. It is based on the prevention of diseases, restoration of soil health, promotion of natural pest control and overall system diversity and resilience. EU-funded projects, studies, and many farmers have demonstrated that IPM techniques can reduce pesticide use by 50-80% or more, while maintaining good vields and profits. Both small-scale and larger-scale farmers across Europe are leading the way, showing that only very exceptionally using pesticides or even fully phasing out of pesticides is possible, by truly implementing Integrated Pest Management through agroecological, organic, restorative and conservation practices¹². IPM has been mandatory in the EU since 2014 under the Sustainable Use of Pesticides Directive (SUD) 2009/128/EC. The Directive establishes 8 mandatory IPM principles, and states that the practices and products with the least possible disruption to agro-ecosystems, and the lowest risk for human health and the environment, always have to be used. The SUD also demands protection of water bodies, protected nature areas and citizens from exposure to synthetic pesticides. However, the Directive remains barely implemented in Member States, as thoroughly

¹² United Nations (2017). Report of the Special Rapporteur on the right to food - UN experts denounce 'myth' pesticides are necessary to feed the world, IPMWORKS project. Reducing pesticide use is a must for the future, Lechenet et al. (2017). Reducing pesticide use while preserving crop productivity and profitability on arable farms, Pecenka et al. (2021). IPM reduces insecticide applications by 95% while maintaining or enhancing crop yields through wild pollinator conservation, INRAE (2022). Protect crops by increasing plant diversity in agricultural areas Magrach et al. (2022). Increasing crop richness and reducing field sizes provide higher yields to pollinator-dependent crops, Rodríguez et al. (2022). Aphid suppression by natural enemies in hedgerows surrounding greenhouses in southern Spain, Nandillon (2024). Pesticide use reduction: evolution of practices and technico-economic performances within farms of the DEPHY network, EARA (2025). Farmer-led Research on Europe's Full Productivity The Realities of Producing More and Better with Less, Nandillon et al. (2024). Crop management strategy redesign enables a reduction in reliance on pesticides: A diachronic approach based on a diversity of French commercial farms, Wäckers. From Pesticide Addiction to Ecological Integrated Pest Management

documented¹³. As a first step, we recommend the European Commission to audit the national or regional transposition of the directive. Furthermore, independent, high-expertise and very regular advice on IPM for all farmers, including on soil restoration and agroecological practices, is a prerequisite for achieving truly resilient, sustainable systems. Both IPM and **independent advisory systems** are mandatory through the SUD. Correct enforcement of the Regulation and Directive is needed to achieve its objectives: implementing IPM - including the uptake of biocontrol within the broader framework of preventative measures, effectively protecting water, nature and citizens from pesticide exposure, and effectively reducing pesticide use and risk.

Next to the need for independent, high-expertise advice on IPM for all farmers, it is key that the **Common Agricultural Policy** (CAP) is transformed into a tool that truly supports farmers to transition out of pesticides. CAP funds should be linked to result-based pesticide reductions during a transition period, and to pesticide-free practices, or practices which only exceptionally use pesticides as a very last resort¹⁴.

Moreover, the EU SPRINT-project includes in its <u>key recommendations</u> for policy-makers the need to support for adoption of agro-ecological practices, restoration of on-farm and landscape-level biodiversity, uptake of **IPM**, in which pesticide-free farming should be the default, allowing chemical use only as a justified exception, strengthened independent advisory networks, and aligning the CAP with the transition needed, prioritising pesticide-free practices and offering tools such as pest-insurance.

Easing access to market for alternatives to synthetic pesticides

Regarding the statement in the Commission's call for evidence that "new alternatives – in particular biopesticides – are slow to reach the market," PAN Europe's statistical analysis of official pesticide approval data¹⁵ paints a different picture. **Approval rates for biocontrol substances have been increasing over the last six years and have now by far overtaken approvals for conventional pesticides**.

In the past six years, between February 2019 and February 2025, 82% of approved active substances were biocontrol agents, almost half of which were microorganisms, compared to 18% synthetic pesticides. In total, according to IBMA, there are about 180 biocontrol active substances in the market based on their definition, which constitutes 46.4% of currently approved active substances at EU level (communication exchange).

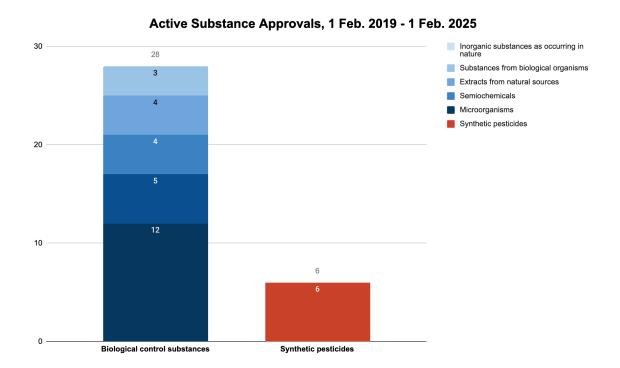
Report on the SUD of the European Court of Auditors (2020)

¹³ Implementation assessment on SUD by the European Parliamentary Research Service (2018) Report on the SUD of the European Commission (2020)

¹⁴ PAN Europe, 2025. <u>CAP post 2027</u> - an opportunity to answer citizens' demands and support farming beyond pesticides, PAN Europe, 2025. <u>Implementation of the outcome of the Strategic Dialogue on Agriculture requires ambitious policy action to reduce pesticides Recommendations for the EU Vision for Agriculture and Food, <u>SPRINT project results</u>, 2025</u>

¹⁵ European Commission's website. Latest updates on Active substances https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/latest

This increase in the approvals of biocontrol substances was anticipated: during the previous Commission mandate, steps were taken to facilitate the approval of microorganisms, including amendments to approval criteria and data requirements.



Evidently, a much higher level of capacity and expertise at both the EU and national levels on biocontrol are needed in order to improve the assessment and authorisation, and therefore availability, of biocontrol.

However, it is essential that robust risk assessment and post-approval monitoring remain in place, and that the key bottleneck is addressed, namely the lack of implementation of IPM. Independent, high-expertise advice on IPM, soil restoration and agroecological practices is a prerequisite to ensure truly robust and future-proof practices are widely taken up. Biocontrol has a valuable role within the broader framework of Integrated Pest Management: it should always be implemented within an IPM system, fully based on active preventative measures, soil restoration and fostering overall resilience, in which, only if additional control is needed, biocontrol is prioritised over other pesticide substances. Rather than focusing on a 1:1 substitution of substances, which is ineffective and unsustainable, biocontrol should be applied within this broader IPM framework, optimising overall resilience of the system against pests and extreme weather events. Only then can biocontrol be fully effective.

Furthermore, it is essential that the **definition of biopesticides** is clearly demarcated, in order to maintain the specific benefits and characteristics of biocontrol: <u>Biocontrol products are natural or nature-identical substances</u>. "Identical" means <u>all the following conditions should be met</u>: 1) containing only naturally occurring amino-acids, 2) the three-dimensional structure is identical,

3) the biological function is not changed, and 4) the biological degradation occurs in a predicted way according to a natural pathway. The definition should explicitly exclude synthetic substances that are merely structurally similar or functionally identical to their naturally occurring counterparts. Heavy metals and their salts should also be excluded from the definition of biocontrol.

Enhanced market access for biocontrol must not result in weaker risk assessments or any dilution of the provisions under Regulation 1107/2009 for a high level of protection from pesticides. We therefore urge the European Commission to pursue a **strictly targeted revision of the Regulation**, limited exclusively to provisions designed to facilitate market access for biocontrol products, while maintaining all existing safety standards.

Delays in pesticide risk assessment

The call for evidence states that: "There are systematic delays in the procedures for approvals and renewals of approvals of active substances, while deadlines laid down in Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market are not met as Member States lack the capacity to process applications on time. "

We agree that systematic delays in pesticide risk assessment are highly problematic. They result in repeated extensions of the approval periods of active substances. These prolongations are increasingly frequent and lengthy. In July 2022, 72% of the substances that are approved as candidates for substitution had received at least one extension of their approval period due to delays in their risk assessment, and in most cases this prolongation had been repeated for several consecutive years. The high number of substances concerned and the fact that many of them end up getting banned once their assessment is completed show that this prolongation pattern hampers the achievement of the high level of protection required by the Regulation. There is therefore a need to address this issue of systematic risk assessment delays.

This should be addressed by ensuring a **stricter enforcement of the Pesticide Regulation**, **particularly its provisions regarding data requirements** (Regulation 283/2013). Indeed, some of the delays in risk assessment are due to the industry's failure to comply with data requirements. This leads to delays in assessments and increases the workload for regulators. Therefore, dossiers that do not comply with Regulation 283/2013, either because of a data gap or because the data are not fit for purpose, should not be considered as admissible and the approval of the substance should be suspended at once.

Systematically, when delays occur in the risk assessment process, the European Commission makes use of **Article 17** of Regulation 1107/2009 to extend the approval periods of the substances concerned. However, when there is already clear evidence of harmful effects, that is, when the substance under assessment does not meet the approval criteria, this practice violates the Regulation, whose aim is to ensure a high level of protection, and is inconsistent with the precautionary principle. For example, the most <u>recent prolongation</u>, adopted at the Standing Committee of Plants Animals Food and Feed meeting in October 2025, concerned a

proposal to extend, among others, the approval period of flurochloridone for 9 months and 15 days, until 31 October 2027. Yet, this candidate for substitution, which was originally approved until May 2021, is classified as toxic for reproduction (category 1B) under Regulation 1272/2008, i.e., is a 'cut-off' substance and no further assessment is required according to Article 4(1) (Regulation 1107/2009). Moreover, it is a per- and polyfluoroalkyl substance (PFAS). Based on its molecular structure (containing a $C-CF_3$ group), it is expected to degrade into TFA. In line with the Regulation, the Commission should refrain from any further prolongation of such a harmful substance: they should be automatically banned shortly after their classification as 'cut-off substances'.

The regulatory workload could also be reduced by applying Article 6(f) on confirmatory information more strictly. Currently, it is common for substances to be renewed with outstanding confirmatory information (missing studies are requested to be submitted after the renewal is granted), while this should remain an exception. In 2025, two synthetic active substances were renewed¹⁶, both with confirmatory information requirements. One of them, quinoline-8-ol (previously 8-hydroxyquinoline), classified as toxic for reproduction category 1B. was renewed under the condition that its use will result in negligible exposure, although this was not realistically proven in the renewal application. The confirmatory information includes requests for data demonstrating the non-dietary exposure, i.e. negligible exposure, of workers and operators under realistic conditions of use, as well as additional data to further investigate the genotoxic potential of the substance. Yet, according to the Opinion of Advocate General Kokott (5 June 2025, Case C-316/24 P), confirmatory information cannot consist of data that should have already been included in the renewal dossier. Moreover, when the confirmatory data submitted by the applicant are insufficient to allow a conclusion, this should result in the withdrawal of the substance, as compliance with the approval criteria has not been demonstrated. In practice, however, such situations lead to lengthy and resource-intensive procedures. The case of pendimethalin clearly illustrates this issue. As a candidate for substitution, confirmatory information intended to clarify whether the substance meets the Persistent Bioaccumulative and Toxic (PBT) cut-off criterion was submitted in late 2018. The subsequent risk assessment of this data, extending beyond the originally required scope, took several years. Only now is the confirmatory information procedure being concluded, with the decision on the substance's bioaccumulative (B) potential still pending.

An increase in resources, including funding and capacity, for EFSA and the competent authorities in Member States is needed to ensure the timely implementation of the pesticide Regulation. However, any additional resources should be strictly conditional upon the conduct of independent, rigorous, and transparent risk assessments. Strengthening and harmonising independence policies across all relevant institutions is important to prevent conflicts of interest and to ensure the credibility of the regulatory process.

Moreover, Member States have the possibility to **raise fees to pesticide applicants** to cope with the costs of risk assessment. Fees should be systematic and set at an amount covering the costs of the risk assessment and risk management procedure.

_

¹⁶ Excluding low-risk and basic substances. The two substances are lenacil (regulation 2025/833) and quinolin-8-ol (Regulation 2025/1152).

Mutual recognition and minor use

The EU definition of "minor use" for pesticide products, as set out in Article 3(26) of Regulation 1107/2009, is broad and grants significant discretion to Member States in determining which uses qualify as 'minor' (e.g. crops grown on a small scale or widely grown but needed exceptionally for plant protection). Given that specific provisions apply to minor uses, including Article 51, which allows for the extension of authorisations without new risk assessment, the definition of a 'minor use' should be clarified and strictly regulated to ensure EU-wide compliance with Regulation 1107/2009, including its Article 50 and the approval criteria aiming under Article 4, which aim to protect human health and the environment.

Currently, some Member States circumvent their obligations under Article 50 for minor uses, undermining the uniform application of the Regulation. Indeed, many do not adequately perform a comparative assessment for authorisation applications, which cover at least one minor use (cf Belgium for instance). This incorrect interpretation of Article 50(1) is encouraged by the EPPO standard 271/3, which suggests that Member States are free to choose whether they consider it appropriate to perform a comparative assessment for minor uses or not. The EPPO decision scheme states the following: "Are minor uses sufficient to stop CA (comparative assessment), according to the available national CA procedure? If yes, stop CA" (page 4). It is evident from both Article 50 and Annex IV that a comparative assessment must be carried out, even when minor uses are involved, and that the potential consequences for those minor uses must be considered within the analysis. Importantly, the comparative assessment should also encompass non-chemical substances and alternative agricultural practices.

With regard to mutual recognition, some Member States conduct a comparative assessment as indicated in their national guidance document (France), while others indicate in their guidance document that this is required prior to granting an authorisation but do not do so in practice (Belgium, Spain).

Data protection

PAN Europe considers that the rules concerning data protection, as defined in Article 3(21) of Regulation 1107/2009, namely, "the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant" must remain fully consistent with the primary objective of the Regulation, which is to ensure a high level of protection of human health and the environment (recital 24). Accordingly, any data indicating the toxicity of a substance should immediately be shared among competent authorities. This also applies to co-formulants, synergists and safeners.

Any modification of the current framework must respect Article 2(1)(d)(vi) of Regulation 1367/2006, as interpreted by the Court of Justice (Case C-673/13 P), which clarified that the public has the right to access information that allows it to verify whether information relating to emissions into the environment were properly assessed and to participate effectively in decision-making.

Furthermore, no revision should undermine the principles and obligations introduced by the Transparency Regulation (Regulation 2019/1381), which strengthened public access to information and required applicants to notify all studies conducted for approval purposes. Recent research by Swedish scientists A. Mie and C. Rudén revealed that certain pesticide industry companies had withheld information on the neurotoxic potential of their substances, which underscores the critical importance of maintaining full transparency and accountability in the pesticide approval process. Such openness is essential to enable independent scientists and civil society to scrutinise the underlying evidence and ensure regulatory decisions are based on complete and reliable data.

Seed treatment

In a ruling from 2023 (<u>Case C-162/21</u>), the Court clarified Article 53(1) of Regulation 1107/2009 is to be interpreted as prohibiting the placing on the market and use of seeds treated with plant protection products, whose placing on the market and use have been expressly prohibited following evaluation by EFSA.

Drone applications

The Commission's text of the consultation on the Food and Feed Safety omnibus refers to the **use of drones** to spray pesticides, as they would allow 'more targeted pesticide application'. The text states that currently the individual applications to use drones require too much administrative burden, and that enabling innovation with the technology of precision drones under 'safe conditions' will help protect human health and the environment.

In this regard, we refer to the SUD (Recital 14 and Article 9), which prohibits the use of aerial spraying, while only allowing derogations for applications of aerial spraying which are bound to individual requests and very specific conditions and requirements: "Aerial spraying of pesticides has the potential to cause significant adverse impacts on human health and the environment, in particular from spray drift. Therefore, aerial spraying should generally be prohibited with derogations possible where it represents clear advantages in terms of reduced impacts on human health and the environment in comparison with other spraying methods, or where there are no viable alternatives, provided that the best available technology to reduce drift is used".

- Overall, it is essential that the use of aerial spraying remains prohibited, and that the use
 of drones for aerial spraying remains subject to the need to individually apply for a
 derogation, linked to specific conditions and requirements.
- It is important that a <u>comprehensive scientific assessment is carried out</u> on the impacts and risks of the use of drones to apply pesticides, particularly synthetic and other harmful ones, including the long-term ecological impacts. Specifically, the use of drones, as it concerns aerial spraying, raises concerns regarding further drift of pesticides, and therefore, higher exposure of the surrounding environment and citizens. Additionally, as the volume that can be loaded on drones is small, the pesticide

substances applied with drones are likely to have higher concentrations, leading to increased risks. Higher localised concentrations can have negative impacts on (soil) biodiversity, crop residue, food safety and health. Risks due to pesticide drift also increase with concentration. For these reasons, a thorough, scientific assessment is needed on the impact of the use of drones on drift, exposure of the environment, citizens and operators, the concentration of the pesticide substances applied, and on the use and risk of pesticides. The impacts of different weather conditions, the flight height, speed and different crops are essential to take into account in such assessments.

- The use of drones, by use of derogation and bound to all above-mentioned requirements, should also only be allowed for the application of natural low-risk pesticides and for the very targeted treatment of specific spots where pests occurred, and after all preventative measures of IPM, to decrease vulnerability to pests, were taken. Effective, sustainable reduction of pesticide use and risk can only take place when preventative measures, focused on soil health, diversification and increased resilience of the cropping system are implemented. The targeted application of pest control should, in line with IPM, always remain a very last resort.
- It is essential that the individual applications and derogations given remain registered by Member States, and that citizens are notified well in advance when drones will be used, as required by the SUD. Any weakening of these requirements would be highly unjustified. On the contrary, it should be required for farmers to indicate on an online public platform when and where they will apply which pesticides, independent of the means of pesticide application (also for non-aerial spraying). Citizens have the right to be informed about when and which pesticides will be sprayed.

Maximum residue levels (MRLs)

The call for Evidence highlights that "terminology and transitional rules on maximum residue levels (MRLs) require clarification to increase legal certainty." We consider that the ongoing Omnibus initiative presents a timely opportunity for the European Commission to address inconsistencies between Regulation 1107/2009 (the Pesticide Regulation) and Regulation 396/2005 on MRLs.

Currently, residues of pesticides banned within the EU continue to be permitted in imported food products. Nearly **65 pesticides prohibited in the EU have MRLs above the limit of detection (LOD)**. In 2022, a total of 53 different EU-banned pesticides were <u>detected</u> in food imports from third countries. This also concerns highly harmful substances meeting the "cut-off" criteria for human health hazards, such as those classified as toxic for reproduction (Repr. 1B).

Table: Repr. 1B active substances with MRLs above 0.01mg/kg or the relevant LOD

Substance Name	Harmonised Classification (date)	Status	Expiration of Approval
Dimethomorph	Repr. 1B (2019)	Not-approved	20/05/2024

Isopyrazam	Repr. 1B (2020)	Not approved	08/06/2022
Mancozeb	Repr. 1B (2019)	Not approved	04/01/2021
Cyproconazole	Repr. 1B (2015)	Not approved	31/05/2021
Thiacloprid	Repr. 1B (2015)	Not approved	03/02/2020
Glufosinate	Repr. 1B	Not approved	31/07/2018
Carbendazim	Repr. 1B, Mut. 1B (2019)	Not approved	30/11/2014

This situation is incompatible with the hazard-based approach of the Pesticide Regulation, which recognises that these substances' intrinsic properties are so hazardous that any exposure poses an unacceptable risk. Only "negligible exposure", meaning 'no human contact and non-detectable residues in food' (below 0.01 mg/kg or the relevant LOD), may exceptionally be accepted under the Pesticide Regulation. However, negligible exposure requirements are disregarded when MRLs are established based on Codex Alimentarius Commission (CXLs) or import tolerance requests. This undermines Article 1 of the MRL Regulation, which seeks to ensure a high level of consumer protection, and Article 3(2)(g), which states that import tolerance should not be set for pesticides that have been banned because of public health reasons.

Moreover, maintaining high MRLs (above LOD) for banned pesticides in imported food puts at risk the income of EU farmers who are transitioning to more sustainable, agro-ecological practices, while toxic pesticides are being phased out. Allowing such residues in imports creates unfair competition and market distortion, contrary to the Commission's stated objectives.

The fact that the cut-off criteria are not reflected in the MRL Regulation and its implementation, creating inconsistency between the Pesticide Regulation and the MRL Regulation, was already highlighted in the 2020 REFIT report by the Commission. In its Farm to Fork Strategy, the Commission pledged to review tolerances for substances meeting the "cut-off criteria" with high human health risks and to consider environmental aspects when assessing import tolerances for pesticide substances no longer approved in the EU. Similarly, in its Vision for Agriculture and Food (19 February 2025), the Commission committed to ensuring that the most hazardous pesticides banned in the EU for health or environmental reasons are not reintroduced via imported products.

The Commission should use the Omnibus initiative to introduce a mechanism under Article 17 allowing MRLs listed in Annexes II and III to be lowered automatically to the default value of 0.01 mg/kg (or the relevant LOQ) whenever the approval of the corresponding active substance has been revoked or not renewed because it does not meet the safety approval criteria under Regulation 1107/2009. Such a process could be applied without seeking a new EFSA opinion. Moreover, the Commission should ensure that all substances banned in the EU for health but also for environmental reasons are covered. In other words,

16

the legal basis for setting MRLs should be broadened to explicitly include environmental protection considerations. This is in line with the NGOs and trade unions' demands.

The Commission should also review its <u>Technical Guideline SANTE/2015/10595</u>, to ensure full consistency with the hazard-based provisions of the Pesticide Regulation.

Biocides

A comprehensive evaluation of the Biocidal Products Regulation (BPR) is scheduled for this year. Any potential adjustments or amendments to the Regulation should be guided by the findings of this evaluation. As stated in the 2021 implementation report, "A full evaluation of the BPR, planned for 2025, will analyse in depth the fitness of the current regulatory framework as a basis for deciding on the need for further action." Introducing changes at this stage through the omnibus procedure could undermine, delay, or even counteract the ongoing evaluation process. We therefore strongly recommend that the BPR be excluded from the omnibus procedure until the results of the comprehensive evaluation are available. Furthermore, we support the position of PAN Germany and urge the European Commission to ensure the full implementation of Regulation No 528/2012 without further delay and to complete the review programme by 2030.

Conclusion

PAN Europe calls on the European Commission to use the "Food and feed safety – simplification omnibus" initiative as an opportunity to strengthen the implementation and enforcement of EU food and feed safety legislation, particularly Regulation 1107/2009 on pesticide approvals and Directive 2009/128/EC on pesticide use as well as Regulation 396/2005 on MRLs. This represents an opportunity for the EU to align better with citizens' repeated demands for more protection and less use of pesticides.

Decades of scientific evidence demonstrate that harmful pesticides, including endocrine disruptors, carcinogenic substances, and substances with developmental neurotoxicity impacts, continue to pose serious risks to human health, wildlife, and ecosystems. Current shortcomings in pesticide risk assessment, prolonged approval periods, and poor enforcement of the legislation undermine its objectives and violate the precautionary principle.

PAN Europe calls on the European Commission to:

 Implement Regulation 1107/2009 rigorously, ensuring that hazardous pesticides are identified and swiftly removed from the market, and that risk assessments fully account for human, animal, and environmental impacts, including all exposure routes, long-term and cumulative effects of formulations, and impacts on amphibians, non-target arthropods, and biodiversity in general.

2. Enforce Directive 2009/128/EC across Member States, ensuring that Integrated Pest Management (IPM) is fully implemented as the mandatory framework for all farmers, and that the practices with the least possible disruption to agro-ecosystems, and the lowest risk for human health and the environment, are always used. Not using pesticides should be the default, with their use permitted only exceptionally, and only after all possible preventative measures have been implemented. Regular, independent, high-expertise advisory services on IPM, agroecological practices, soil restoration and overall resilience-building measures are essential. Water bodies, protected nature areas and citizens should be effectively protected against exposure to pesticides. As a first step, we recommend the European Commission to audit the national or regional transposition of the directive.

- Facilitate the uptake of biocontrol products within the IPM framework, while
 maintaining robust risk assessment standards and clarifying the definition of biocontrol to
 exclude synthetic substances merely resembling natural ones, as well as heavy metals
 and their salts.
- 4. Ensure that Maximum Residue Levels (MRLs) reflect the hazard-based approach, automatically setting the MRLs of banned substances at the default value (0.01 mg/kg or the relevant LOQ), and that import tolerances do not reintroduce hazardous pesticides into the European market. EU citizens and farmers must be protected from unfair competition and toxic exposure alike.
- 5. **Maintain strict transparency** and public access to all studies and data submitted for pesticide approval, ensuring independent scrutiny and accountability.
- 6. **Exclude the Biocidal Products Regulation (BPR) from this omnibus** until the results of the planned evaluation are available, avoiding confusion and regulatory backtracking.
- 7. Ensure the Common Agricultural Policy is transformed into an instrument fit for purpose to support the phase out of pesticides. CAP funds should be fully conditioned on meeting the obligations of the pesticide legislation and the result-based reduction and phase out of pesticides.
- Replace the Harmonised Risk Indicator (HRI-1), which is scientifically unfounded and provides misleading, incorrect information about the trends in pesticide use and risk, with a scientifically robust indicator.
- 9. **Ensure electronic registration of pesticide use** is implemented without delay, in line with Regulations 1107/2009, 2022/2379 and 2023/564.

Strengthening enforcement, ensuring rapid removal of harmful substances, and promoting sustainable, ecologically sound alternatives are not only legally required but also essential to protect public health, preserve biodiversity, and secure resilient food systems for European

citizens. The Commission has the tools to act decisively. PAN Europe urges it to do so without

Contact:

delay.

Pesticide Action Network Europe (PAN Europe) Rue de la Pacification 67, 1000 Brussels, Belgium www.pan-europe.info

Tel. +32 2 318 62 55



Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or CINEA. Neither the European Union nor the granting authority can be held responsible for them.