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NORSK INSTITUTT FOR
BIOØKONOMI

European Commission

Date: 22.05.2026
Our ref.: 26/01160
Your ref.: COM (2025) 1030, 2025/0410 (COD)

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Feedback on the Food and Feed Safety – Simplification Omnibus – Amendments to Regulation (EC) No 1107/2009

The European Commission has launched a broad initiative to simplify and modernise existing legislation on the authorisation and use of plant protection substances and products. The objective is to reduce unnecessary regulatory burdens, increase the efficiency of implementation and ensure that the regulatory framework is better adapted to current needs. The proposal responds to repeated requests from stakeholders and EU Member States for faster and clearer regulatory procedures. A key consideration is securing the food and feed supply while maintaining high standards for the protection of human and animal health and the environment.

Feedback period: 18 December 2025 to 25 May 2026.

The Norwegian Institute of Bioeconomy Research (NIBIO) is an independent research institute. NIBIO contributes to food security and safety, sustainable resource management, innovation and value creation through research and knowledge production in food, forestry and other biobased industries. NIBIO is generally positive to the proposal. Nevertheless, NIBIO wishes to comment on relevant aspects related to Regulation (EC) No 1107/2009 and Directive 2009/128/EC.

This feedback has been professionally compiled by Director Marianne Stenrød and Researcher Anette Sundbye in the Division of Biotechnology and Plant Health (DBP).

Proposal to amend Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 governs the placing of plant protection products on the market. The Commission proposes several amendments, including measures to facilitate and accelerate



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the placing on the market of new biological plant protection products and to reduce the time required to authorise plant protection products. In summary, the proposed changes include:

- Introducing a clear definition of substances considered to be biocontrol substances (such as micro-organisms, semiochemicals and plant extracts).
- Requiring applications for biocontrol substances and biological plant protection products to be prioritised.
- Allowing provisional authorisations for plant protection products containing new biocontrol substances, even if the approval process has not been fully completed.
- Establishing a single assessment area (one zone) in the EU for authorising plant protection products that contain only biocontrol substances or low-risk active substances.
- Allowing Member States to request extended support from EFSA (the European Food Safety Authority) in the evaluation process.
- Approving most active substances without a time limit, with certain exceptions (while products containing such substances will still receive time-limited product authorisations).
- Clarifying how the concept of “current scientific and technical knowledge” should be interpreted to achieve better harmonisation among Member States in the assessment process.
- Exempting farmers from keeping spray records when using products containing only biocontrol substances (*).
- Simplifying the criteria for approval of low-risk substances.
- Introducing a strengthened system for mutual recognition of biocontrol and low-risk substances, including a provision that authorisation is deemed granted if a country does not respond within 120 days, thereby improving access to plant protection products in small countries and small markets.
- Introducing longer transitional periods when approvals are withdrawn, to allow more time for adjustment where alternatives are lacking.
- Simplifying the rules on extensions to minor uses.
- Simplifying the special provision in Article 4(7), which allows exemptions from the approval requirements for substances in cases of acute risk to plant health.
- Clarifying the rules for approval of basic substances, including their placing on the market and labelling for plant protection purposes, as well as resolving dual-approval uncertainties.
- Clarifying the rules for treated seeds.
- Introducing a single data protection system for the entire EU.
- Facilitating improved access to plant protection products for controlling quarantine pests by prioritising such applications and establishing a single approval area.

NIBIO's comments

NIBIO considers that these changes are positive, except for the point on record-keeping (underlined *), where farmers would be exempted from keeping records when using products containing only biocontrol substances. This is mentioned in the Proposal document, pp. 2-3, 19, 30 and 59-60. Although reducing the administrative workload is beneficial, this would likely result in a lack of statistics on the use of such products. Such statistics are important for



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monitoring trends in the use of biological plant protection products over time, both in terms of overall volume, the crops in which they are used and the pests they target. Official statistics from Statistics Norway (SSB) currently provide a knowledge base on the use of chemical and biological pesticides, across different crops and production systems. Such data are essential for authorities to monitor usage patterns, assess progress in action plans for sustainable plant protection and adapt regulations and policy measures accordingly.

In addition, the Norwegian Food Safety Authority (Mattilsynet) compiles official statistics on the sale of plant protection substances, which provide an indication of market trends. However, without sufficient registration of actual use, it will be difficult to obtain a picture of how biological control substances are applied in practice. This may weaken both the knowledge base for regulatory decision-making and the ability to document the effects of a transition towards more sustainable plant protection measures.

NIBIO therefore recommends that the record-keeping obligation should not be removed entirely. A simplified reporting requirement, preferably through a digital and low-burden solution, would reduce administrative work for farmers while still securing the data needed to monitor the use of biological plant protection products. The mandatory record keeping from 1 January 2026 according to Regulation (EU) 2023/564, stating that *'farmers and spray operators using plant protection products (PPPs) must keep detailed, electronic, machine-readable records'*, would allow for a low-demand and standardized record keeping for all groups of plant protection products, including biocontrol substances. Further, such records including all spraying practices will help/enable the assessment of the achievement of the mandatory requirement of IPM detailed in Directive 2009/128/EC; i.e. sections (18), (19) and (20) in the current Directive, stating the requirements to promote, facilitate and assess implementation of IPM in the member countries as well as *'measure the progress in reducing the risks and adverse impacts from pesticide use for human health and the environment'*. In our opinion such record keeping will improve current tools in this regard significantly. We also point to potential requirements and synergies with the mandatory reporting on pesticide indicators under the Convention on Biological Diversity but have not done a thorough assessment of this here.

NIBIO also notes that simplification of the rules on extensions to minor uses is particularly relevant for small markets and speciality crops. Clearer and more harmonised procedures, including improved possibilities for mutual recognition, may improve access to plant protection products where the commercial market is too limited to support ordinary authorisation pathways.

The proposed Simplification Omnibus is expected to require adjustments to Norway's national implementation of Regulation (EC) No 1107/2009, including adaptations to more streamlined regulatory procedures. It is also likely to increase both the pace and volume of application assessments and authorisations of products with biocontrol substances. For NIBIO, this implies greater demand for rapid scientific assessments related to biocontrol. In addition, there will be increased reliance on expert agronomic judgements to support national decision-making.

Proposal to amend Directive 2009/128/EC

With regards to the proposed changes in Directive 2009/128/EC, adding the specific mention of unmanned aircraft systems (drones), we look favorably on the specification that *'it is necessary to identify the types of unmanned aircraft systems that have lower or equal risks as regards human health and the environment compared to the risks arising from land-based application*



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equipment for the same use'. As commented in the Call for evidence, targeted/precision pesticide application is not mainly conducted by drones but rather by other technological platforms such as robots and precision equipment attached to the spray equipment that the farmer already has. The precise use of pesticides by drones would require the building and standardization of drones, nozzles etc that may be used for precise pesticide application in specific crops.

Yours sincerely

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