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European Commission

CALL FOR EVIDENCE
FOR AN INITIATIVE (without an impact assessment)

TITLE OF THE INITIATIVE	Food and feed safety – simplification omnibus
LEAD DG – RESPONSIBLE UNIT	DG SANTE E.4, R.1
LIKELY TYPE OF INITIATIVE	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1107/2009, Regulation (EC) No 396/2005, Regulation (EU) No 528/2012, Regulation (EC) 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation 1099/2009, Regulation (EC) No 999/2001, Regulation (EC) No 1069/2009, Regulation (EU) 2017/625, Directive 98/58/EC and Directive 2009/128/EC as regards simplifying and strengthening food and feed safety requirements
INDICATIVE TIMING	Q4 2025
ADDITIONAL INFORMATION	--

This document is for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described, including its timing, are subject to change.

A. Political context, problem definition and subsidiarity check

Political context

This proposal is part of the cross-cutting legislative simplification package announced in the European Commission's *Vision for Agriculture and Food*. The aim of the package is to reduce unnecessary regulatory burdens while maintaining high standards for food and feed safety, for human and animal health, and for environmental protection. The proposal **responds to repeated requests from stakeholders and EU countries for faster, clearer procedures** for plant protection products, drones, biocides, feed additives, hygiene rules and official controls. The proposal contributes to the Commission's overarching objectives to:

- **streamline the EU regulatory framework** in line with the *Communication on a simpler and faster Europe*;
- **improve the competitiveness and resilience of EU food and feed systems**, building on the *Competitiveness Compass*;
- achieve the simplification targets of reducing regulatory burden by **25% for companies** and **35% for Small and Medium-sized Enterprises** – this includes cutting recurring administrative costs by **EUR 37.5 billion** by the end of the current Commission's mandate, without undermining policy objectives.

In recent years, the Commission has regularly gathered and assessed input from Member States and stakeholders on how to simplify food and feed safety rules and reduce administrative burdens, including those linked to reporting obligations. This proposal builds on that feedback and aims to deliver a concrete contribution to the Commission's broader simplification agenda.

In particular, the initiative proposes targeted simplification measures in several areas:

- authorisation and renewal procedures for plant protection products and biocidal products;
- clarifications related to terminology and transitional measures for the setting of maximum residue levels for pesticides, the modification and renewal of authorisations, and labelling requirements for feed additives, including digital labelling options;
- notification procedures for national hygiene measures;
- the Bovine Spongiform Encephalopathy (BSE) surveillance and risk management framework;
- flexibility in official checks of plant consignments at border control posts;
- accreditation requirements for reference laboratories;

- clarification related to the legal status of fermentation products manufactured using genetically modified micro-organisms (GMMs); and
- more targeted pesticide application by drones under safe conditions.

These proposals build on the findings of recent evaluations of EU legislation, including the pesticides legislation (SWD(2020) 87 final) and the Feed Additives Regulation (SWD(2024) 46 final).

Problem the initiative aims to tackle

Plant protection products: Farmers face a shrinking toolbox as older products lose authorisation and new alternatives – in particular biopesticides – are slow to reach the market. Slow approval of biopesticides makes it difficult to reap the competitive benefits of these substances, including on international markets. 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. Meanwhile, the mutual recognition of product authorisations and extensions for minor uses is not functioning as intended, leading to unequal availability of plant protection products to farmers in different Member States and difficulties in applying the provisions of the Plant Health Regulation (Regulation (EU) No 2016/2031) that prevent unacceptable impacts on agricultural production in the EU. Clarification of the provisions on basic substances, seed treatment and data protection is needed in order to achieve a more harmonised implementation across Member States. Lastly, drones can allow more targeted pesticide application, but the administrative burden of individual farmer applications for drone use is hampering their development.

Maximum residue levels: Terminology and transitional rules on maximum residue levels (MRLs) require clarification to increase legal certainty.

Biocidal Products Regulation: The 2021 Report on the implementation of Regulation (EU) No 528/2012 identified significant problems hampering the proper functioning of the regulatory system. The programme for reviewing existing active substances suffers from persistent delays, affecting both the approval of these substances and product authorisation. These issues hinder market access and discourage innovation. Concerns have also emerged around the expiry of data protection for all existing active substances in 2025.

Feed additives: The 2024 evaluation of the Feed Additives Regulation (Regulation (EC) No 1831/2003) identified several potential areas for simplification. In particular, the 10-year renewal requirement imposes high administrative and financial costs on businesses. Procedures for modifying authorisations, including a change of holder, also involve an unnecessary burden, one that can be reduced. In addition, labelling rules for feed additives are not fully aligned with those for feed materials and compound feed, creating inconsistencies and added burden.

Hygiene rules: Member States face procedural inefficiencies due to overlapping notification systems under the Hygiene Regulations and the TRIS Directive, making it unclear which procedure applies and when.

Bovine spongiform encephalopathy (BSE): The current rules under Regulation (EC) No 999/2001 on BSE are outdated and limit the EU's ability to respond swiftly to new risk assessments, scientific developments and evolving international standards. As the level of disease risk from BSE has fallen, the surveillance requirements, rules on specified risk materials (SRMs), and trade restrictions on certain commodities are no longer considered proportionate. These provisions impose unnecessary burdens on competent authorities and food business operators, creating regulatory and operational challenges.

Official Controls Regulation: currently, border control posts cannot release the compliant part of a consignment if another part still needs further checks. This often leads to unnecessary delays, especially for plant consignments made up of different batches with varying control requirements. Also, the accreditation rules for reference laboratories are too rigid and do not consider the specific needs of areas like plant pests or feed additives, causing ongoing compliance issues.

Animal welfare: Member States must submit annual depopulation reports under Regulation 1099/2009 on the protection of animals at the time of killing, even though similar information is already included in the annual reports under the Official Controls Regulation. This overlap creates extra work for national authorities and the Commission, without adding value.

Fermentation products: operators and Member States face a challenge in determining whether food and feed products produced using GMMs in a fermentation process constitute food and feed "produced from GMOs" (subject to the GMO legislation) or "food produced with GMOs" (outside the GMO legislation). This creates regulatory uncertainty and divergent enforcement practices.

Basis for EU action (legal basis and subsidiarity check)

Legal basis

The legal basis consists of:

- Article 37(2), Article 95 and Article 152(4)(b) of the Treaty establishing the European Community; and
- Article 43(2), Article 49, Article 114, Article 168(4)(b) and Article 192(1) of the Treaty on the Functioning of the European Union (TFEU).

Practical need for EU action

The areas covered by this initiative are regulated at EU level through specific regulations and directives. The aim of the legislation is to harmonise the internal market and ensure a high level of protection for human and animal health and the environment. Simplification can be most effectively achieved by amending the underlying legal acts through the ordinary legislative procedure. It cannot be achieved by Member State action alone.

B. What does the initiative aim to achieve and how

The initiative aims to simplify, clarify and modernise selected provisions across several pieces of EU food and feed safety legislation. It responds to long-standing calls from stakeholders and Member States to reduce administrative burden, improve legal clarity and increase the efficiency of regulatory procedures. More specifically, this initiative aims to remove unnecessary complexity, enable innovation and strengthen the functioning of the internal market. These measures aim to reduce administrative burden for economic operators and national competent authorities, while maintaining a high level of protection for human, animal and environmental health.

Plant protection products: By reducing administrative burdens for both industry and Member State competent authorities, the proposal aims to help EU farmers and the broader food and feed sector become more competitive and to prevent unacceptable impacts on agricultural production, as provided for in the Plant Health Regulation (Regulation (EU) No 2016/2031).

For marketing authorisations for plant protection products, the proposal aims to accelerate access to innovative biocontrol solutions. This will be achieved by tackling procedural inefficiencies and reallocating or increasing resources in Member State authorities and the European Food Safety Authority. These resources are currently tied up with routine renewal obligations for active substances and products.

The proposal also intends to expand market access for plant protection products through stronger mutual recognition of product authorisations between Member States and strengthened support for minor uses.

In addition, the proposal intends to clarify provisions related to basic substances, seed treatment and data protection to increase harmonisation of implementation across Member States.

Collectively, these changes are intended to accelerate procedures and reduce delays, ease regulatory workload, and improve the availability of alternative crop protection tools (in particular to chemical pesticides) across the EU.

Finally, enabling innovation with technology of precision drones under safe conditions will help protect human health and the environment.

Maximum residue levels: The proposal aims to improve the clarity of terminology and transitional rules in order to increase legal certainty.

Biocidal products: The initiative proposes a limited set of targeted adjustments to the Biocidal Products Regulation in order to address specific issues already identified in practice, ahead of the full evaluation of the Regulation, scheduled to begin in 2025. These measures aim to reduce administrative burden for economic operators and national competent authorities, allowing them to focus resources on completing the review programme of existing active substances. This in turn would help ensure that all biocidal products placed on the market undergo proper authorisation procedures under harmonised rules, increasing the level of safety across all Member States. The Commission is also examining whether amending the expiry date of all data protection for existing active substances could achieve a more balanced approach between the rights of review programme participants and those of other stakeholders.

Feed additives: The initiative aims to reduce the regulatory and administrative burden for businesses, as well as for Member States and the European Food Safety Authority, which are involved in the authorisation process. It focuses on simplifying and clarifying: (i) rules on the modification of authorisations, such as in cases where there is a change to the authorisation holder; and (ii) the regime for renewing such authorisations. These adjustments are intended to ease compliance costs without compromising the high level of protection or compromising user interests. The initiative also considers introducing more flexibility in labelling requirements, including the use of digital labelling for certain non-safety information.

On **hygiene rules**, the initiative aims to streamline the notification of national hygiene measures by aligning procedures with Directive (EU) 2015/1535 (the Technical Regulation Information System (TRIS) Directive). A single, harmonised notification system would simplify compliance, promote adaptation of hygiene rules to national circumstances and improve transparency through the TRIS database.

On **BSE,** the initiative aims to revise the legal framework to allow timely updates based on scientific risk assessments. It seeks to modernise disease control measures and introduce a more flexible, science-based approach at EU level. This will ensure regulatory consistency, reduce regulatory pressure on food business operators and facilitate trade.

Under the **Official Controls Regulation**, the initiative aims to allow partial clearance of consignments of plants and plant products at border control posts. This responds to practical challenges in cases where phytosanitary certificates cover diverse batches requiring different types of checks; Member States have consistently called for flexibility to avoid trade delays when only part of a consignment is held up. The proposal also considers introducing a limited derogation from accreditation requirements for reference laboratories. This would address compliance issues, better reflect technical specificities, and respond to repeated requests from Member States and the European Commission's Joint Research Centre, while preserving the integrity of EU rules.

On **animal welfare**, the proposal aims to reduce the administrative burden on Member State competent authorities by no longer requiring them to submit an annual report on depopulation operations.

For **fermentation products** where GMMs are used as production strains, the proposal aims at clarifying whether the resulting food and feed is to be considered "produced from" or "produced with" GMMs.

Likely impacts

The proposal is expected to reduce administrative burdens for economic operators and Member State authorities. Compliance costs are expected to fall, while a high level of safety for human health, animal health and the environment will continue to be maintained. The proposal is also expected to help EU farmers become more competitive.

By making the approval system for active substances more efficient for plant protection products and biocidal products, and in particular speeding up market access for biocontrol active substances for plant protection products, we are likely to see reduced costs and faster return on investment for companies placing such substances and (products containing them) on the market. Combined with measures to strengthen mutual recognition of product authorisations and measures to allow greater future use of drones in precision farming, farmers are expected to benefit from access to more crop protection tools.

By simplifying the authorisation rules for feed additives, particularly on renewal periods and changes to existing authorisations, we expect to see reduced costs, greater efficiency, and support for innovation, especially for small and medium-sized businesses, without compromising a high level of health and environmental protection. This would boost the competitiveness of the EU feed sector and make the EU market more attractive for investment. The initiative also introduces the option for digital labelling under certain conditions, which is expected to lower compliance costs and increase flexibility. To ensure safe use, essential safety information would remain on physical labels. Existing safeguards allow for the modification, suspension or revocation of authorisations where needed, ensuring continued protection of food and feed safety.

On hygiene rules specifically, the proposal is likely to have a positive impact on Member State initiatives to adapt the rules to local needs. This will increase flexibility and result in lower costs.

For the Official Controls Regulation, introducing an option for partial clearance of consignments of plants and plant products would simplify Member States' border control procedures, while operators would avoid the heavy financial consequences associated with undue delays in trade and the destruction of perishable goods. For reference laboratories, full accreditation for every analysis method can be costly and time-consuming, especially for new or rarely used techniques. This potentially limits innovation and can slow down urgent responses to emerging challenges. The exemption from accreditation requirements would encourage the development of new methodologies while maintaining fundamental quality standards.

On BSE, adapting the requirements for surveillance, specified risk material (SRM) management and certain bovine-derived commodities is expected to reduce the administrative burden on competent authorities and lower compliance costs for food business operators. Overall, the initiative will ensure that the regulatory framework remains scientifically sound, proportionate and responsive.

On food and feed fermentation products manufactured using GMMs, the clarification introduced will reduce compliance and enforcement costs.

Future monitoring

The initiative's impact will be monitored through existing reporting and oversight mechanisms in each sector. This will form part of the regular follow-up of the relevant legislation.

For **plant protection products**, monitoring will focus on application numbers, review timelines and authorisations for biocontrol products. For **biocides**, progress on the active substance review programme and product authorisations will be tracked. For **feed additives**, monitoring will focus on key indicators including innovation activity, application trends and the availability of feed additives on the EU market.

For **official controls**, the Commission will monitor the use of new flexibilities for partial consignment release. For **BSE**, future monitoring will focus on data related to testing volumes, updates to specified risk material procedures, and further developments in the trade of certain bovine-derived commodities.

For **hygiene rules**, the focus will be on how the simplified notification procedure is implemented and its effect on transparency and efficiency.

C. Better regulation

Impact assessment

This simplification initiative does not require a full impact assessment as the policy choices to address the very specific problems are limited. Its design is based on existing evidence, including:

- past evaluations and an impact assessment (e.g. of the pesticides legislation and the Feed Additives Regulation);
- implementation reports (e.g. on the Biocidal Products Regulation); and
- structured input from Member States and stakeholders, collected through regular exchanges and consultations.

The proposed simplification measures are highly technical in nature. There are no viable alternatives to achieving the objectives, and the proposed measures do not alter core policy objectives or introduce significant new obligations. For these reasons, additional public consultation or a full impact assessment would not bring added value.

Instead, the proposal will be accompanied by an analytical staff working document. The document will clearly explain the proposed measures and present the underlying evidence, analysis and stakeholders' views, while also estimating the potential cost savings.

Consultation strategy

While no additional consultations are envisaged at this stage, stakeholders have already provided numerous suggestions and position papers and are invited to share further views and suggestions via this call for evidence. Contributions will be considered during the proposal's preparation, particularly where they provide practical insight or flag unintended consequences. This feedback opportunity enables stakeholders to support efforts to streamline procedures. Input will be considered especially where it highlights operational challenges, innovative practices, unnecessary burdens, or potential for further cost savings. Relevant contributors may include:

- farmers' organisations and trade associations;
- Member State competent authorities;
- manufacturers and importers of plant protection and biocidal products;
- food and feed business operators, and their industry associations;
- NGOs, members of the public and other interested parties;
- research institutions and academia.