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Simplification Omnibus Package

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Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements

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Glossary

Term or acronym	Meaning or definition
BSE	Bovine Spongiform Encephalopathy
CAP	Common Agricultural Policy
COPHS	Council Working Party of Chief Officers of Plant Health Services
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EP	European Parliament
ESFC	E-Submission Food Chain platform
EU	European Union
EURL	European Union Reference Laboratory
EURL-FA	European Union Reference Laboratory for feed additives
FA	Feed Additives
FCM	Food Contact Materials
GMM / GMO	Genetically Modified Micro-Organism
JRC	Joint Research Centre of the European Commission
MEP	Member of the European Parliament
MRL	Maximum Residue Level
MS	Member States

OCR	Official Controls Regulation
NRL	National Reference Laboratory
PPP	Plant Protection Products
RASFF	Rapid Alert System for Food and Feed
RMS	Rapporteur Member State
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
SME	Small and Medium-sized Enterprise
SRM	Surveillance Risk Material
SUD	Sustainable Use Directive
TFEU	Treaty on the Functioning of the European Union
TSE	Transmissible Spongiform Encephalopathy
WOAH	World Organisation for Animal Health

1. INTRODUCTION

The EU's food and feed safety legal framework is one of the most robust in the world. It safeguards human, animal and plant health, enables smooth functioning of Europe's Single Market, and underpins our global reputation for high standards. To remain effective, this framework must also evolve: becoming simpler, faster and more innovation-friendly, while maintaining its high level of protection for Europeans.

For the 2024–2029 mandate, President von der Leyen set out a clear ambition: to make Europe's regulatory environment more supportive of competitiveness, sustainability and resilience, while keeping protection high. Europe must ensure that regulation empowers, rather than slows down, the twin green and digital transitions. The Commission's simplification agenda was framed by the Communication on *A simpler and faster Europe*.[1] This set quantified targets to reduce administrative costs by 25% for all companies and 35% for SMEs by the end of this mandate, which will translate to EUR 37.5 billion in savings for businesses. To operationalise these commitments, the Commission launched a series of *Omnibus simplification packages*. These have already demonstrated that policy objectives can be preserved while reducing burdens, as shown in areas such as sustainability reporting, customs and climate instruments.[2]

This ambition to *"make business easier and faster"* is particularly relevant for the agri-food sector. Europe's farmers, food producers and consumers expect a framework that guarantees safety and trust, while also enabling investment and new market opportunities. The *Strategic Dialogue on the future of agriculture and food*, conducted in 2024, confirmed that the regulatory environment must enable operators to innovate and adapt, while ensuring that the EU's high safety and sustainability standards are maintained. Its conclusions informed the Commission's *Vision for Agriculture and Food*. This roadmap highlights that simplification and access to innovation are essential for a competitive, resilient and fair agri-food system. By contrast, excessive administrative requirements, outdated control mechanisms and rigid and repetitive authorisation systems impose unnecessary costs and delay, creating substantial barriers to competitiveness, innovation and efficient risk management.

Delivering on the *Vision* requires concrete legislative action, as shown by the Commission's proposals for targeted simplification measures in agriculture since 2024. These respond to direct calls from farmers and Member States for proportionate rules and lighter administrative requirements. In March 2024, a first simplification package of the Common Agricultural Policy (CAP) proposed to exempt farms under ten hectares from conditionality controls and penalties, streamlined amendments to CAP Strategic Plans, and revised several Good Agricultural and Environmental Conditions (GAECs) to give Member States and farmers greater flexibility.[3] The broad political consensus on the need to reduce administrative burden was confirmed by the conclusion of the negotiations between co-legislators within weeks. Since adoption, these changes have already reduced compliance costs and eased implementation for both farmers and competent authorities while maintaining strict environmental standards.[4]

1 COM(2025) 47 final
2 COM(2025) 81 final, COM(2025)84 final, COM(2025)526 final, COM(2025)531 final
3 COM(2024) XXX final
4 SWD(2024)360 final

In May 2025, the Commission followed up with another CAP simplification proposal to eliminate the annual performance certification mechanism, streamline the procedure of amending Strategic Plans, and modify conditionality further. Additionally, the Commission introduced new flexibility in the provision of crisis payments and increased the amount of lump-sum support that small producers could receive. This proposal alone is projected to reduce administrative costs for farmers by up to EUR 1.58 billion annually, with particular benefits for small and medium-sized farms. Combined, the two packages are anticipated to generate substantial cost savings.

Alongside CAP, simplification has been pursued in related areas of the agri-food acquis. A proposal to amend the Fertilising Products Regulation, part of the Omnibus on chemicals, aims to reduce duplication in conformity assessment and to enable digital labelling, cutting costs for operators while facilitating oversight.[5] The ongoing revision of the plant reproductive material (PRM) legislation likewise aims to clarify notification and reporting rules, modernise procedures, and remove inconsistencies across Member States.[6] A proposal to create a framework for plants obtained by certain new genomic techniques (NGTs)[7] would also streamline current rules and benefit farmers, consumers, and the environment. These initiatives confirm a consistent direction of travel while maintaining the Union's high level of protection and policy ambition.

The next step in implementing the *Vision* is to extend simplification beyond agriculture into the wider food and feed safety acquis, with the aim to enhance resilience, sustainability and investment in the sectors for the benefit of farmers and citizens. This omnibus proposal accompanied by this Staff Working Document responds to clear signals from Member States, economic operators and other stakeholders that rules can be streamlined, and procedures made more efficient. It introduces a package of targeted measures across the acquis, covering not only authorisation/approval procedures but also systematic renewal of authorisations/approvals, mutual recognition, surveillance, reporting and other areas where obligations have become unnecessarily complex or costly. By streamlining these processes, aligning risk management with current scientific knowledge and international standards, and creating more agile pathways for safe and sustainable innovations, the initiative reduces administrative burden for operators and administrations alike, while strengthens the competitiveness and resilience of the EU food chain.

The initiative builds on a substantial evidence base. The evaluation of the Plant Protection Products (PPP) and Maximum Residue Levels (MRL) legislation identified lengthy and resource-intensive procedures, insufficient resources in Member States authorities to conduct tasks assigned to them, limited incentives for low-risk and biological solutions, and legal uncertainty around transition periods when MRLs[8]. The evaluation of the Feed Additives (FA) [9] modernise labelling requirements for feed additives.[10] Evidence from the implementation of the Biocidal Products Regulation, and the implementation of the Official Controls Regulation (OCR) [11] highlighted obligations that could be simplified without lowering the level of protection. Together, these findings provide a robust analytical foundation for the Omnibus, complemented by stakeholders'

5 COM(2025) 531 final
6 COM(2023) 414 final
7 COM(2023)411 final
8 SWD(2020) 262 final
9 SWD(2024) 46 final
10 In particular COM(2021) 287 final and SWD(2021) 128 final
11 COM(2021) 350 final

and Member States' input received through Standing Committees, advisory groups and dedicated consultations.

The Union's food and feed safety acquis is anchored in a set of horizontal and sectoral acts, including the General Food Law Regulation (EC) No 178/2002, the hygiene package, the Official Controls Regulation (EU) 2017/625, and legislation on plant health, animal health and welfare, feed, biocidal products, maximum residue levels (MRLs), and genetically modified food and feed. These acts together ensure a high level of protection while supporting the functioning of the Single Market. Evaluations, implementation experience and stakeholder inputs have pointed to specific procedural obligations that can be made more efficient without lowering safety standards.

Against this background, the proposal introduces targeted amendments to a defined set of legal acts in the food and feed safety acquis. These include: Regulation (EC) No 1107/2009 (plant protection products), Regulation (EC) No 396/2005 (MRLs), Directive 2009/128/EC (sustainable use of pesticides), Regulation (EU) No 528/2012 (biocidal products), Regulation (EC) No 1831/2003 (feed additives), Regulation (EC) No 852/2004 (food hygiene), Regulation (EU) 2017/625 (official controls), Regulation (EC) No 1829/2003 (GM food and feed), and Regulation (EC) No 999/2001 (TSEs). The package focuses on selected procedural and administrative elements within these acts, without modifying the underlying risk-assessment principles or the Union's level of protection.

This Staff Working Document accompanies the Commission simplification proposal (omnibus) amending selected acts in the field of food and feed safety. This omnibus has been structured as a package comprising a proposal for a regulation amending several regulations, a proposal for a directive amending several directives, and a targeted proposal to amend Article 95 of the Biocidal Products Regulation on data protection. More specifically, this document includes a presentation of the main issues identified, an analysis of the proposed measures and the specific problems addressed, the views of stakeholders and Member States, the objectives pursued, and an assessment of expected impacts, in particular the reduction of administrative burden and costs for food business operators and national administrations.

2. MAIN ISSUES

EU food and feed safety legislation has evolved over time into a comprehensive and trusted framework, protecting public, animal and environmental health and ensuring the functioning of the internal market.[12][13] Evaluations and implementation experience, however, show that the incremental build-up of detailed procedures can create frictions and administrative costs that are no longer proportionate to their added value. With more mature administrations, improved scientific capabilities and decades of operational experience, there is scope to simplify and modernise specific procedural elements without affecting the level of protection. [14]Innovation is

12 The Bovine Spongiform Encephalopathy (BSE) crisis in the 1990s was a turning point that prompted a rapid expansion and tightening of EU food safety legislation, including the adoption of Regulation (EC) No 178/2002. Subsequent incidents, such as dioxin contamination in feed and residues of unauthorised substances in imports, further embedded precautionary and risk-based approaches.

13 According to the September 2025 Special Eurobarometer on food safety, there is strong citizen confidence in the EU's food safety framework.

14 OECD (2025), *Regulatory Policy Outlook.*

increasingly central to productivity and sustainability in the agri-food system.[15][16] However, in several areas, legislative procedures have not kept pace with technological developments, slowing the uptake of safe and beneficial solutions and increasing transaction costs for operators.[17] Faster decisions, clearer procedural arrangements and the use of digital information tools can help reduce unnecessary formalities and enable faster access to safe innovations while preserving high safety standards.

Over time, certain recurring obligations in the food and feed safety acquis have led to administrative requirements that are no longer proportionate to their added value, particularly for SMEs and for authorities with limited capacity. Evaluations point to systematic renewals, mutual-recognition procedures and the modification of existing authorisations as areas where significant resources are spent without corresponding improvements in safety outcomes. [18]

In parallel, several authorisation and renewal systems have become difficult to manage efficiently. Procedures often involve sequential steps, duplicated checks and extensive documentation, and legal timelines are frequently missed.[19] These inefficiencies create uncertainty for operators, especially SMEs, and contribute to backlogs for administrations.[20] Evidence from cross-cutting evaluations and international practice indicates that clearer procedural rules, reduced duplication and more risk-based approaches would support timely and predictable regulatory outcomes. [21]

Differences in national implementation add to these challenges. Diverging interpretations of reporting, notification or mutual recognition obligations can lead to inconsistent application across Member States, increasing compliance costs for operators active in multiple markets and limiting the effectiveness of internal market provisions.[22] Addressing this fragmentation would improve consistency and reduce unnecessary administrative friction.

Finally, some parts of the acquis have not kept pace with scientific developments or updates to international standards. Outdated analytical terminology, rigid procedures and limited flexibility to integrate new evidence can increase compliance costs and make certain provisions more stringent than necessary. Targeted adjustments to enable timely, evidence-based updates and alignment with international guidance would preserve the Union's high level of protection while improving regulatory coherence.

These five challenges, barriers to innovation, disproportionate burdens, procedural inefficiencies, fragmentation across Member States, and misalignment with science and international standards, illustrate how a framework that remains fundamentally sound can nevertheless create unnecessary costs and delays. Simplification, therefore, provides an opportunity to recalibrate the acquis and maintain the same high level of protection while reducing complexity, freeing up resources, and

15 World Bank (2020). *Harvesting Prosperity: Technology and Productivity Growth in Agriculture.*
16 OECD (2019), *Innovation, Productivity and Sustainability in Food and Agriculture: Main Findings from Country Reviews and Policy Lessons.*
17 See the PPP evaluation (SWD(2020) 87 final)
18 e.g. SWD(2024) 46; SWD(2020) 87; consultation feedback; ongoing evaluation of EFSA performance 2017 - 2024
19 COM(2021) 350 final
20 European Court of Auditors (2020), *Sustainable use of plant protection products: limited progress in measuring and reducing risks* (Special Report 05/2020).
21 OECD (2021), *Improving Regulatory Delivery in Food Safety: Mitigating Old and New Risks, and Fostering Recovery*
22 COM(2020) 93 final

enabling innovation. The following section sets out targeted legislative adjustments that address these systemic issues. Each measure is designed to tackle one or more of the problems identified above, thereby facilitating the uptake of new solutions, lowering administrative burden, and streamlining procedures. In this way, the initiative delivers directly on the objectives of the *Vision for Agriculture and Food* and the Commission's broader agenda for sustainable prosperity and competitiveness.

3. MEASURES

3.1. Faster access to markets and innovation

3.1.1. Biocontrol plant protection products (PPP)

Biocontrol substances offer farmers lower-concern plant protection "tools", such as micro-organisms, semiochemicals (e.g. pheromones) and substances of biological origin or synthetic substances equivalent to naturally occurring substances, that can reduce reliance on hazardous synthetic chemicals while maintaining crop protection performance. Today, however, biocontrol products reach EU markets too slowly and unevenly because procedures to let them access the market take too long, the zonal system for authorisation and mutual recognition of authorisations between Member States underperforms, and assessment capacity is not adapted to their specific needs, e.g., lack of life scientists, microbiologists, as repeatedly flagged by stakeholders and Member States.

Clarifying what qualifies as "biocontrol" and accelerating market access is a core strand of the simplification announced in the Commission's *Vision for Agriculture and Food* and in the European Parliament resolution on *Ensuring the faster registration and uptake of biological control agents*[23]. This proposal realises that commitment by defining biocontrol substances and prioritising their assessment and authorisation of the products containing them, including tools such as provisional product authorisations while approval procedures are still ongoing, a one-zone approach for authorisations and tacit-agreement for mutual recognition if procedural deadlines are not respected, and the option to choose EFSA as rapporteur for the initial safety assessment, so that safe, innovative products reach farmers faster without lowering the level of protection or undermining the internal market. This initiative would not compromise the current levels of protection as the obligation to comply with safety standards and to perform a sound risk assessment would stay the same. For instance, when acting as Rapporteur Member State (RMS), EFSA would be obliged to employ different experts between the RMS and the peer-review assessment, to guarantee an independency between the two processes

In the absence of a harmonised legal definition of "biocontrol substance", competent authorities apply different categorisations to comparable materials (e.g. plant extracts, micro-organism–derived metabolites, or synthetic molecules identical to naturally occurring ones). This results in divergent implementation of data requirements (e.g., how to apply waivers for biological active substances dossiers when they have a chemical nature), additional pre-assessment exchanges to determine the applicable track, and increased use of clock-stops to require additional data. For instance, several biocontrol substances (such as micro-organism-derived metabolites) have a chemical nature, but generally a safer risk profile than other synthetic chemicals. This means that

[23] https://oeil.europarl.europa.eu/oeil/en/procedure-file?reference=2025/2086(INI)

for these biocontrol substances with a chemical nature some data might not need to be submitted in a dossier for their approval, if scientifically justified, due to their nature. This might be true for data concerning the persistency of them in nature after application of a PPP containing them, due to their natural occurrence and low persistency. Defining "biocontrol substance" would help in harmonising the understanding across Member States on how to implement the data requirements, avoiding those frictions which nowadays translate into long timelines. At active-substance level, the time taken by Member States to assess dossiers routinely exceeds the legal benchmark: internal monitoring from May 2024 shows that rapporteur Member States take an average of 3 years and 274 days to draft assessment reports for approvals and renewals of approvals of biocontrol actives. Further delays occur in the product authorisation stage, where again deadlines for zonal and mutual-recognition procedures are not respected.

Mutual recognition of authorisations is not delivering timely or predictable outcomes. Divergent national practices in dossier handling and categorisation (e.g. product considered as a biocontrol agent or not, extra data requirements), frequent clock-stops to clarify scope and implementation of data requirements and missed legal timelines lead to heterogeneous and delayed decisions across Member States. Smaller markets are particularly affected, as lower sales potential coupled with delayed decisions reduce incentives for companies to even apply for authorisation.

Capacity constraints compound these issues. Rapporteur, co-rapporteur, zonal reference and concerned authorities operate with limited assessment capacity. There is no consistent prioritisation of procedures for biocontrol substances and PPP containing them, which reduces the predictability of work planning for biocontrol manufacturers, with some MS even unable to prioritise due to national laws. Where EFSA participates, its scientific capacity is also finite and must be allocated across competing priorities. Specialist expertise on how to assess biocontrol peculiarities is not uniformly available. Gaps in harmonised scientific consensus and experience with e.g., semiochemicals, microbial metabolites and complex plant extracts lead to additional pre-assessment exchanges between applicants and Member States to determine data needs and applicable templates. These exchanges are frequently followed by clock-stops with requests for additional data, which prolong evaluations and create queues that are difficult to clear once formed.

Procedures for the renewal of approvals consume the most substantial share of the assessment capacity of Member State authorities and EFSA. Applicants' regulatory teams are drawn into renewal cycles as well, but the binding constraint on throughput is the authorities' capacity. Resources currently occupied with the recurrent workload from renewals and time lost in assessment due to insufficient harmonisation reduces strongly capacity for the initial assessments of applications for new substances and thus slows the entry of innovative biocontrol solutions into the evaluation pipeline.

Finally, where the Rapporteur Member State has assessed the biocontrol substance and has concluded that it may be expected to satisfy the safety requirements, there is no mechanism to enable earlier market access for PPPs containing new innovative biocontrol substances while the peer review of the initial assessment and decision-making on the EU approval of the active substance is still pending. As a result, procedures for the authorisation of products cannot start even when the initial scientific assessment is already substantially developed at rapporteur level.

The impacts of these bottlenecks are broad and uneven. Applicants for biocontrol substances, an SME-dominated segment with thinner capital buffers, face long and uncertain timelines that raise

financing costs, heighten cash-flow risk, and in some cases threaten business continuity. Stakeholder submissions indicate lost sales of EUR 1 to 3.7 million per product, per year of delay, underscoring the segment's acute sensitivity to time-to-market. Farmers, especially in smaller Member States, experience a narrower and less predictable toolbox for protecting crops: uneven or late availability of biocontrol products leads to continued reliance on synthetic chemistry the variety of which is decreasing, complicating e.g. resistance management, and can lead to higher control costs or yield losses when newer options are not accessible in time for the growing season.

Member States competent authorities face inefficiencies arising from fragmented practices, e.g. different implementation of assessment criteria, need for repeated requests for additional data, and workload related to renewal procedures that crowd out first assessments. Missed mutual-recognition deadlines increase case handling and disputes. At Member State and EU level, scientific capacity is finite and there is no systematic prioritisation lane for biocontrol substances and products, which contributes to queues. For the internal market and farmers, fragmented availability delays the uptake of lower-concern biocontrol products, distorts competition, and risks eroding confidence in proportionate, science-based regulation making the EU less attractive, as there is no true single market for plant protection products, and no strong incentives for bringing such products to the market compared to other regions in the world.

The lack of a clear definition of biocontrol leads to scope ambiguity, divergence in assessment practices, and slow throughput. Commission monitoring of pending applications (May 2024) highlighted substantial delays at the active-substance stage, and casework shows repeated deadline overruns at product and mutual-recognition stages. Operational feedback gathered through informal exchanges, inputs from Member State coordinators, and discussions with rapporteur and zonal authorities consistently points to capacity bottlenecks, renewal-driven crowd-out of new dossiers, and uneven use of existing procedural flexibilities, e.g. mutual recognition. Targeted outreach and stakeholder submissions reinforce this picture, indicating disproportionate burdens on SMEs and quantifying delay-driven revenue losses.

Member States support clarifying scope and making timelines predictable and enforceable, and they call for practical means of reducing duplication while preserving high level of protection. Manufacturers, especially SMEs, seek a clear definition, prioritised handling of applications for biocontrol substances and PPP with lower-concern profiles, earlier product-level access when assessment is advanced, and mutual-recognition outcomes delivered within legal deadlines. Farmers' organisations support faster and more even availability of biocontrol PPP across the Union to strengthen resistance management and reduce reliance on older chemistry, with predictability of availability ahead of critical production windows. NGOs and academia are generally open to streamlining provided safety is maintained, and they underline the need for transparency, meaningful monitoring indicators, and safeguards that ensure a high level of protection for human, animal and environmental health. If the issues are not addressed, backlogs and missed availability for growing seasons will persist, SMEs will defer or abandon innovation, smaller markets will remain underserved, and the credibility of streamlining commitments will diminish.

This omnibus proposal removes these procedural frictions for biocontrol tools while preserving the EU's high level of protection. It clarifies scope, accelerates assessments, enables earlier product access under safeguards such as provisional authorisation of biocontrol products when a RMS risk assessment is positively concluded, and makes mutual recognition work more

predictably across the internal market, while maintaining protection standards. The measures below are designed to operate together:

- Create an EU-level definition of "biocontrol substance" that covers e.g., micro-organisms, semiochemicals (including pheromones), plant extracts, micro-organism-derived metabolites, and synthetically produced substances that are identical to those occurring in nature, which will be identified in a Commission-maintained list of approved active substances.
- Require Member States to prioritise applications for biocontrol substances and related PPPs in their work programmes.
- Allow provisional authorisations for PPPs containing new biocontrol substances when the rapporteur Member State has completed a satisfactory assessment, enabling safeguarded, time-limited market access pending the peer-review and EU approval decision on the active substance.
- Facilitate the authorisation procedure for biocontrol PPPs by applying a one-zone approach for zonal assessment.
- Strengthen zonal authorisation system and mutual recognition for biocontrol PPPs by introducing tacit agreement where legal deadlines are exceeded, so that authorisations are deemed granted if time limits are not respected.
- Offer the option to applicants to choose EFSA as rapporteur for the initial assessment of applications for new biocontrol substances, paired with additional resources for EFSA.
- Remove the record-keeping obligation for professional users where a PPP contains only biocontrol substances.

The expected improvements can be monitored through a series of potential indicators for biocontrol, including for example median substance and product assessment times, the number of (provisional) authorisations, accelerations in mutual-recognition timelines, and availability of biocontrol PPP by Member State. The Commission will provide continued implementation support through the development or update of relevant guidance documents on categorisation, dossier templates and data requirements for semiochemicals[24][25]

Apart from these actions directly targeted to biocontrol substances and products, horizontal changes to the overall PPP framework (see section 3.2.1 – PPP), applicable to all pesticides amplify the biocontrol package by boosting throughput and predictability across the board. Unlimited approvals for most active substances free capacity for the assessment of applications for new biocontrol substances, a clearer EU data-protection regime facilitates fair data sharing and clarifies the end date for data protection which is crucial for market access for SMEs; streamlined mutual-recognition rules and rules for extensions of authorisations for minor uses improve availability of PPP across Member States and a clarified concept of what constitutes "most recent scientific advice" reduce burden for Member States authorities and risk of litigation and expand practical access, while high protection standards are maintained through targeted review mechanisms for more problematic active substances and products, triggered by new scientific evidence or concerns while continuing to periodically review PPPs, whose authorisations remain limited in time. .

[25] implementation support is already provided by existing guidance documents such as: PAFF-PPL-October 2023-Doc.A.07.01, SANTE/2020/12260, SANCO/0253/2008, SANCO/11470/2012, SANTE/12815/2014.

Translating these measures into outcomes, the combined effect is earlier access, fewer repeat procedures, and materially lower costs for applicants and reduced burdens on authorities. Unlimited approvals for biocontrol active substances are expected to save applicants about EUR 6.5 million per year by removing repeated renewal cycles.[26]

Faster access to the market then adds a material commercial benefit: using a mid-point of the underlying estimates, provisional authorisations avert roughly EUR 22 million per year in delayed-marketing losses, and tacit mutual-recognition outcomes avoid a further EUR 1.2 million per year where deadlines are missed. Taken together, these effects cut recurring administrative effort, improve planning certainty, and shorten time to market. Because SMEs make up about 90% of biocontrol manufacturers, they capture most of the gain: for renewals alone, their savings are approximately EUR 5.9 million per year. In a segment where some micro-firms report that preparing a dossier for a biocontrol active substance can cost 1.5 years of turnover, the scale of these savings is significant.

For authorities, unlimited approvals reduce burdens for conducting renewal assessments and, together with clearer categorisation of products, cut pre-assessment exchanges. This allows Member State competent authorities and, where involved, EFSA, to reallocate effort from repetitive renewals to initial assessments of new biocontrol dossiers, raising throughput while maintaining the high level of protection, as active substances and products must comply with safety standards. Delays in authorisations of biocontrol and low-risk PPP are reduced due to a one-zone assessment across all Member States, which reduces case handling and disputes stemming from divergent categorisations or delayed decisions. Combined with enforceable outcomes (including tacit agreements for zonal authorisations and mutual recognitions where deadlines are missed, more consistent delivery across Member States and a more predictable workload for administrations are achieved.

While precise effects are not quantifiable with current data, earlier and more even access to biocontrol and low-risk PPP across the Union enlarges the toolbox for farmers, creates a more level playing field among Member States, strengthens resistance-management strategies, and lowers the risk of yield losses associated with delayed availability of innovative biocontrol products. A targeted derogation from record-keeping where a PPP contains only biocontrol actives further facilitates the handling of biocontrol PPPs by farmers and lowers routine compliance tasks and can encourage uptake without shifting any risk onto users or consumers.

At single-market level, consistent delivery of authorisations helps to ensure access to biocontrol solutions for farmers across all Member States, supporting competitiveness and reducing disparity in access to lower-concern tools, relevant particularly in smaller Member States with historically low application numbers. Stakeholders broadly support improving access to biocontrol solutions, while warning that biological substances cannot yet replace many chemical PPPs one-to-one and stressing the need to maintain high protection standards. All accelerated routes, priority handling, provisional authorisations and strengthened mutual recognition, remain fully anchored in existing EU safety requirements, including interfaces with MRL procedures. These measures uphold the EU's high level of protection for human, animal and environmental health and, within those safeguards, facilitate access to tools that are generally of low concern, advancing sustainability

[26] For more detail on the cost saving calculations, view section 1 of Annex III on methodology

and delivering tangible benefits for consumers and citizens through lower residues in food, a cleaner environment, and strengthened confidence in the safety of Europe's food supply.

3.1.2. Aerial spraying of PPP by drones

Drone technology is transforming crop protection globally, with hundreds of thousands of units already in use and a rapidly expanding market projected to exceed EUR 3 billion by 2033. Drones enable highly targeted application of PPPs, with potential benefits for sustainability, farmer safety and competitiveness. In the EU, however, the Sustainable Use of Pesticides Directive (SUD) imposes a general prohibition on aerial spraying, including by drones, unless a specific derogation is granted by national authorities.[27] This regime has resulted in fragmented practices across Member States, limited uptake of drones for plant protection purposes, and high administrative burden for both operators and competent authorities.

Stakeholders in the Strategic Dialogue on the Future of EU Agriculture, Members of the European Parliament, and a majority of Member States are calling for concrete steps to enable the uptake of precision technologies, particularly drones. At the December 2024 AGRIFISH Council, most Member States urged the Commission to present *"without delay"* clear guidance and a legislative proposal on drone use, including procedures for risk assessment and management.[28] This momentum has been reinforced by Parliamentary Questions from across the spectrum.

Member States report that important knowledge gaps remain on how drones perform in practice, including technical specifications, drift behaviour and other parameters that are critical to determine safe conditions of use. This uncertainty directly affects the way derogations are handled under the SUD and adds considerably to the administrative burden for farmers and national authorities. The 2022 evaluation of the Directive confirmed that the lack of clarity creates disproportionate costs and slows down innovation. Stakeholders have also stressed that drones are the technology most held back by the current framework, even though drones could contribute to more sustainable pesticide use.

Another major obstacle is the absence of a harmonised EU methodology for assessing risks under Regulation (EC) No 1107/2009 when PPPs are to be applied by drones. Without a common approach, Member States struggle to evaluate applications consistently, which in turn prevents wider use across the Union. There is broad agreement that EU-level guidance is needed to provide clarity, ensure a high level of protection and support the safe deployment of drone technology in crop protection.

The lack of a harmonised EU framework also weakens incentives for innovation. Uncertainty about the conditions under which drones can be used safely, combined with the need for individual derogations in each Member State, means that companies cannot be confident that investments in drone technology or in PPP authorisations for aerial use will pay off. This discourages both R&D

27 Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, pp. 71–86, ELI: http://data.europa.eu/eli/dir/2009/128/oj).
28 Council of the European Union (2024), *Precision farming – Council conclusions on the use of new technologies in agriculture*

and market entry, limiting the development of a European drone services sector for PPP application, and slows down the availability of innovative crop protection solutions for farmers.[29]

There are certain initiatives already underway to generate the evidence that would close the knowledge gaps on applications of PPP by drones. The OECD is developing a comprehensive set of tools to support risk assessment, including a database of drift data, empirical models, drone design classifications, guidance on mixing and cleaning, and an ISO standard on spray distribution, as well as recommendations for risk assessors and managers.[30] In parallel, the EU's Horizon Europe framework programme has funded projects that demonstrate the usefulness of drones in agriculture, explore their scalability and provide indications on where further research should be directed.[31]

To build on this knowledge base, the Commission will request the European Food Safety Authority to develop scientific guidance on how to assess and authorise PPPs for aerial application by drones under Regulation (EC) No 1107/2009. In addition, the Commission will consult EFSA and Member States when the Commission prepares a delegated act identifying the types of drones that have lower or equal risks compared to the risks arising from land-based pesticide application equipment for the same use. This approach ensures that any future facilitation of drone use is anchored in a science-based assessment and therefore does not adversely affect the policy objective of maintaining a high level of protection of human health and the environment.

Given the current data gaps, no immediate exemptions for drones from the need for individual derogations are envisaged. Instead, this package proposes to amend the Sustainable Use of Pesticides Directive to create an empowerment for the Commission to adopt a delegated act identifying the types of drones that have lower or equal risks compared to the risks arising from land-based pesticide application equipment for the same use. Subsequently, Member States could exempt these types of drones from the prohibition on aerial spraying. To ensure the framework remains future-proof, the identified types of drones could be amended in future in line with emerging scientific consensus. However, apart from specific conditions concerning pesticide use, any proposal would not set new rules and conditions for unmanned aircraft system operations and would act within the general aviation safety framework.

The amendment of the SUD is expected to provide a strong impetus to the development and deployment of innovative drone technologies adapted to the Union market. The creation of a clear and uniform legal framework, setting strict but predictable conditions, will give stakeholders, and in particular SMEs, the confidence to plan and invest in the drone services sector. This legal certainty is likely to stimulate further R&I projects and facilitate the safe uptake of precision spraying and the targeted application of pesticides explicitly authorised for aerial use. While PPP users will be better placed to benefit from this fast-evolving technology, stakeholder views vary, with many citizens and NGOs expressing concerns about drift and exposure risks, while

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29 Maritan, E. (2025). *An agroecological assessment of uncrewed aerial vehicle spraying in Greek viticulture*

30 See Guiding principles, processes, and criteria for the work of the OECD Drone/UASS Subgroup of the Working Party on Pesticides; OECD Report on the State of the Knowledge – Literature Review on Unmanned Aerial Spray Systems in Agriculture; ISO 23117-2:2025 Agricultural and forestry machinery — Unmanned aerial spraying systems, Part 2: Test methods to assess the horizontal transverse spray distribution.

31 ICAERUS focuses on drone monitoring and spraying and improved decision-making for pesticide reduction. SPADE develops a multi-purpose drone model to support precision farming. GO DRONSafe addresses safe application, aiming to reduce human and environmental exposure. FORTUNA identifies research gaps and promotes precision application and digital technologies to monitor pests.

businesses support enabling drone use under strict, harmonised risk-management and operator-competence rules. As exemptions would only apply to drone types shown to have risks equal to or lower than land-based applications, the measure is not expected to adversely affect, and may even support, the objective of reducing the risks associated with pesticide use.

The precise cost benefits cannot yet be quantified, but evidence indicates considerable potential, particularly in challenging agricultural settings such as steep slopes, tall vertical crops and difficult terrain. In such contexts, drones can reduce labour intensity, increase operational efficiency and deliver measurable savings. In other settings, the balance of benefits will depend on factors such as equipment costs, maintenance and lifespan, but may shift further in favour of drones as labour and input costs rise.

Looking ahead, drones are expected to play a central role in the wider digital transformation of agriculture. Combined with automated crop surveillance, weather monitoring and precision input management, they offer multiple opportunities to reduce costs, labour and chemical use. Low-altitude drones can improve the targeted delivery of PPPs, reduce drift and use, and thus optimise efficient and sustainable crop production.[32]

Overall, by creating a predictable and future-proof framework, the measure will make drones a practical and safe tool for precision farming in the Union. This will contribute directly to the Commission's policy objectives of reducing the use and risk of pesticides, protecting biodiversity and pollinators, and minimising exposure of workers, bystanders and the environment, while at the same time fostering innovation, competitiveness and resilience in the agri-food sector.

3.2. Lowering administrative burdens

3.2.1. Further PPP simplification

In a second strand of measures beyond biocontrol (see chapter 3.1.1), this omnibus proposes targeted simplifications to Regulation (EC) No 1107/2009 that relate to most pesticides, including biocontrol substances and products. The proposal responds directly to the findings of the evaluation[33] of the EU pesticides legislation, which highlighted persistent non-compliance with statutory timelines, uneven implementation across Member States, and administrative practices that add burden without commensurate gains in safety. These bottlenecks slow down access to safe, innovative products and create fragmentation in availability of PPP across the Union. They also absorb a large share of the finite assessment capacity of Member States and EFSA, leaving less room for first assessments of new, more sustainable solutions. By simplifying procedures and clarifying legal concepts, the package addresses the structural issues that affect all PPPs, complementing and reinforcing the dedicated biocontrol track presented in 3.1.1. t

These measures pursue three objectives:

- streamline approvals by removing systematic renewal of approval obligations for most active substances

32 Calderone, G., Ferro, M.V. and Catania, P. (2025), *A systematic literature review on recent unmanned aerial spraying systems applications in orchards*, Smart Agricultural Technology, vol. 10.
33 COM/2020/208 final

- make the single market work better by reinforcing mutual recognition of authorisations and simplifying procedural requirements for applicants
- improve legal clarity and fair competition by reducing uncertainty and ensuring a level playing field, especially for SMEs and new entrants.

More specifically, this omnibus proposes:

- unlimited approvals for most active substances with the possibility for selecting such substances for full renewal procedure and introducing a new provision to allow for targeted reassessment (including for substances with limited approval) in addition to maintaining the possibility for review of approval under Article 21;
- enhanced mutual recognition with reduced documentation requirements for applicants; simplified requirements for minor-use extensions;
- data-protection coherence via clear, EU-wide rules on start/end of protection;
- clarification regarding basic substances;
- closure of implementation gaps on treated seeds.

These measures do not alter the fundamental protection standards enshrined in Regulation (EC) No 1107/2009; new provisions will allow the Commission to identify active substances with unlimited approval to undergo either a full renewal process or targeted reassessment (including targeted reassessments for active substances with limited approval). Substance selection will involve consultation of the Authority, consider requests of Member States and will be based on specific criteria. This will create a more agile approach with an accelerated uptake of new scientific or technical knowledge and a more rapid response to emerging issues. In practice, this means that rather than reassessing all substances at fixed time intervals, authorities can focus effort where scientific progress points to a possible change in the risk profile.

The current level of protection for human and animal health and the environment will be maintained and can be expected to increase. Therefore, the policy objectives underpinning Regulation (EC) No 1107/2009 are maintained. All the existing risk assessment requirements and procedures remain in force: while the periodic time-driven renewal of the approval of active substances is removed. Safeguards remain to ensure active substances with unlimited approvals can still be reviewed at any time where new evidence emerges that this is necessary in view of protection of human health or the environment. The package is limited to improving procedural efficiency and legal clarity; it does not change the existing strict approval criteria or the possibility of review when needed.

Overall, the measures will deliver significantly lower administrative burden for authorities and applicants and increase predictability for the availability of PPPs to farmers. For administrations, freeing up capacity from repetitive renewals allows more timely assessments of new applications and a clearer focus on substances or products that raise specific concerns. For businesses, in particular SMEs, fewer routine procedures and clearer rules on mutual recognition and data protection reduce compliance costs and investment risk. These changes support the Union's broader priorities on competitiveness by making authorisations, and thus farmers' toolboxes, more predictable. Targeted reassessments will focus effort where risks are highest, therefore maintaining the Union's high level of protection for health and the environment.

Unlimited approvals with possibility for full renewal or targeted reassessments

Today, approvals of all active substances are time-limited and require renewal applications at least three years before expiry. This systematic cycle, based on time rather than needs, generates very high volumes of work for Member States and EFSA and obliges applicants to prepare costly dossiers. The evaluation of PPP legislation found persistent delays across the system. These affect initial approvals, renewals and the timing of downstream decisions on authorisation and availability of PPPs. The result of these processes is heavy administrative effort, growing backlogs and ever slower processing of applications for new active substances and products. Capacity is locked into routine calendar-driven tasks rather than directed to more relevant reviews that are necessary to ensure that high safety requirements are maintained. This has been confirmed by several stakeholders in response to the Call for Evidence.

For competent authorities, recurring renewal procedures for active substances strain resources, make statutory timelines harder to meet and increase demands on EFSA. For companies, renewal dossiers for active substances must be assembled years in advance and renewal of PPP authorisations requires additional dossiers to be prepared. Fees and data costs are high, planning is complex, and timelines become uncertain as delays and queues lengthen. Smaller firms are hit hardest because fixed costs are spread over fewer products and markets. For farmers and other professional users, slower decisions at both substance and product levels delay access to new and innovative PPPs and keep existing portfolios in frequent reassessment, reducing predictability and following non-renewals of approvals of active substances, limiting available tools in the field.

Overall, the current renewal model absorbs assessment capacity without a commensurate gain in protection: effort is spent re-checking substances on a fixed schedule rather than targeting specific concerns or new evidence. This reinforces delays and increases administrative burden across the system. It also means that the same intensive renewal process is applied to all substances, irrespective of their risk profile.

Moreover, it is important to recall that as of 2025, all approved active substances have been fully assessed at least once by Member States and EFSA, with many being subject to a full renewal assessment and in a few cases a second renewal assessment. In December 2025, 210 active substances are currently subject to an ongoing renewal procedure, which will continue even once the new rules are in place. Hence, for most of these substances, only at the finalisation of the ongoing renewal procedure –a decision will be taken on whether approval can become unlimited or not. The current standard is therefore very high, allowing to move towards a system of unlimited approvals for some active substances with possibility for full renewal or targeted reassessment to ensure standards are maintained. It is expected that targeted reassessments will accelerate the uptake of new scientific or technical knowledge and respond to emerging issue more rapidly.

Approvals of most active substances will become unlimited with the exception of active substances that are candidates for substitution, active substances approved under the derogation possibility set out in Article 4(7) of Regulation (EC) No 1107/2009 and active substances for which a limited time of approval is set in accordance with Article 6 as such active substances have properties that are of concern with regards to human or animal health or the environment, and cases where the outcome of the assessment or other legitimate factors indicate that a time limit is appropriate. The Commission will set the framework for work programmes that may select specific active substances for a full renewal procedure or a targeted reassessment (which can also be applied to active substances with limited approvals). In addition, the current possibility for ad-hoc reviews under Article 21 for specific substances is retained and may be used where new evidence or developments arise over time and where an active substance is not being reviewed or

reassessed under a specific work programme. It is important to note that the authorisation of plant protection products will remain limited in time and therefore products will continue to be periodically reviewed.

The new provisions therefore allow for various assessment possibilities: full renewal of active substances with unlimited approval, targeted reassessment of active substances with unlimited or limited approval, while review at any time in accordance with Article 21 is maintained. Together these provisions ensure sufficient safeguards to maintain the high protection standards already in place, as requested by many stakeholders in response to the Call for Evidence. Following renewal or targeted reassessment of active substances, PPPs will also be re-examined at Member State level. Article 56 obligations for authorisation holders to inform authorities of potentially harmful effects from use of PPPs continue to apply. The possibilities set out in Article 44 for Member States to amend or withdraw authorisations where Article 29 requirements are no longer met remain fully operable, and so do the provisions of Article 69 and 71 (safeguard measures for immediate market withdrawal in case of serious risks) ensuring action can be taken promptly if new risks emerge.

Shifting from periodic renewals to unlimited approval for most active substances, with the possibility for full renewal or targeted reassessments, will free resources in Member States, so that authorities can meet legal deadlines and prioritise assessments of applications for new active substances and new PPP. This will help innovative products reach farmers faster. Manufacturers will avoid routine renewal fees and dossier costs and can redirect spending to developing alternatives and bringing new or improved products to market.

At active-substance level, shifting from routine to targeted renewals avoids repeated dossier build-ups, i.e. study updates, data formatting, expert consultancy, submission management, and related regulatory fees, delivering about EUR 49.6 million in cost savings per year for non-biological substances.[34]

Beyond costs, farmers' toolboxes will grow. Faster assessment of new active substances and a more stable PPP portfolio will increase availability of innovative and lower-concern PPPs. The change from systematic to targeted renewals of approval of active substances will also help reduce *in vivo* animal testing, supporting the objectives of Directive 2010/63/EU on the protection of animals used for scientific purposes.

Essential-use derogation

The current essential-use derogation in Article 4(7) of the PPP Regulation is too narrow to operate in practice. Although this provision allows time-limited approval of an active substance that does not meet certain hazard-based approval criteria, no substance has ever been approved under it. Instead, Member States have to resort to extensive use of Article 53 of the PPP Regulation to grant time-limited emergency authorisations when an active substance is needed to control a serious danger to plant health or crop production that cannot be contained by other reasonable means. If products would be authorised under such derogation, the obligation to prepare phasing-out plans adds administrative burden on Member States.

[34] For more detail on the cost saving calculations, view section 1 of Annex III on methodology

This proposal clarifies the scope of the essential-use derogation so that, for a limited period, an active substance may be approved even if a broader range of approval criteria are not met, where it is necessary to control a serious danger to plant health or plant production that cannot be contained by other reasonable means, while excluding substances with certain hazards of particular concern for health or the environment. It removes the obligation for Member States to draw up phasing-out plans when they authorise products containing such substances.

The changes give competent authorities workable tools to respond to serious plant-health risks without the need to resort to emergency authorisations. Farmers and other professional users will have more predictability, reducing the risk of production shocks where alternatives are limited. Applicants, manufacturers and distributors benefit from greater predictability and a lower risk of stock write-offs at market exit. Safeguards remain intact, since the derogation stays exceptional and MRLs must be established to ensure consumer safety, as well as mitigation measures being put in place to minimise exposure.

Enhanced mutual recognition

The authorisation of a PPP granted by one Member State is meant to be accepted by other Member States where agricultural, plant-health and environmental conditions are comparable. Such 'mutual recognition' aims to avoid repeating the same assessment, reduce administrative effort, and ensure that farmers have more even access to PPPs across the Union. In practice, evidence from the evaluation, the Zonal Authorisation Procedure- Improvements and Development (ZAPID) workshop held in December 2023[35] and stakeholder feedback shows timelines for completion of mutual recognition applications far beyond the four months set out in the Regulation.[36] Typical durations are seven to ten months, and newer stakeholder data indicate around twelve months.

Delays are caused by multiple factors, for example applicants who are not the holder of the original authorisation face extra steps such as securing the holder's consent or proving public interest for the specific PPP use, which makes submissions by official or scientific bodies and professional agricultural organisations harder. This omnibus proposes changes to that mutual recognition works as intended. It makes the dossier requirements lighter in certain cases, with particular attention to applications from entities that are not the holder of the original authorisation for which mutual recognition is sought. Specific enhancements for biocontrol products are addressed separately (see section 3.1.1).

These measures will make applications easier to prepare and process. Mutual recognition is cheaper than a full authorisation, so lifting unnecessary steps should raise the number of applications and the number of authorisations, even if the exact savings cannot be calculated in advance. In parallel, the proposal will bring about shorter timelines and procedures should move closer to the four months set in the Regulation. Faster market entry for PPPs in more Member States would be the result of such improvements. As explained in section 3.1.1, for biocontrol

[35]https://food.ec.europa.eu/document/download/21e6b162-ac20-4d3c-aefb-a9084888f515_en?filename=pesticides_auth-ppp_workshop_20231205_sum.pdf

36 https://food.ec.europa.eu/plants/pesticides/authorisation-plant-protection-products/assessment-plant-protection-products-ppps_en

products, the enhanced mutual recognition route with tacit agreement is expected to speed up access to PPPs even further.

Applicants for mutual recognition, many of them SMEs, will gain from lower procedural effort and earlier market access. Farmers will benefit from wider and more even availability across the Union, including in smaller markets, giving them more choice of solutions. Overall, the level of protection will remain unchanged, while the measures will support farmers' competitiveness.

Simplification for low-risk active substances

The identification of low-risk active substances is not straight-forward to apply in practice because Article 22 of the PPP Regulation ties the low-risk status of an active substance to specific hazard criteria for that active substance and to Article 47 which concerns low-risk PPPs and refers to requirements in relation to specific risk mitigation measures for which fulfilment is not known at the time of approval or renewal of the active substance since the assessment of the product is the second step in the procedure. Authorities and applicants cannot confirm at approval stage whether the product criteria will be met, which blocks or delays low-risk status of active substances, which in turn is a precondition for low-risk status of a PPP containing it. Under the current rules the status of an active substance cannot be changed after approval. Because the low-risk status depends on product-level criteria that are not known at approval or renewal, substances that could qualify as low-risk often cannot receive that status until the first renewal. This delays access to the low-risk route, creates unequal treatment, and adds unnecessary burden for applicants and farmers who cannot benefit from simplified procedures for PPP authorisation during the initial approval period.

The omnibus proposes to base low-risk identification only on the intrinsic properties of the active substance and to allow for the submission of an application to change the status of an already approved active substance to low-risk. This makes the status more easily confirmable at approval and enables easier reclassification later if the criteria are met. This is expected to facilitate application procedures for low-risk active substances and to reduce administrative burden for applicants, encouraging development and placing on the market of more products containing such substances. It supports the reduction target for hazardous pesticides and expands the farmers' toolbox with more sustainable options.

Facilitating minor-use extensions

Extensions of PPP authorisations for minor uses (i.e. small acreage or specialty crops) are hampered by some conditions in Article 51 of the PPP Regulation that stakeholders consider too restrictive. Implementation also varies significantly across Member States. Procedures and expectations differ, creating uncertainty for applicants and farmers and leading to uneven access to products for minor uses across the Union. Limited transparency and weak sharing of good practices compound these divergences. Current rules constrain the mutual recognition of authorisations across borders for minor uses, especially when the use in the reference Member State is not itself classified as minor. Together, these factors discourage applications for economically important but small-scale uses and leave farmers with too few pest-management options.

This proposal simplifies and aligns the minor-use route across the Union. It removes conditions that have made conditions for minor-use extensions overly restrictive, enables mutual recognition

of minor-use authorisations even when the reference use is not classified as minor. It also empowers the Commission for setting out harmonised procedures, so that Member States follow the same steps and documentation for minor-use extensions and for mutual recognition, with greater transparency and systematic sharing of good practices.

The simplified and aligned minor-use route makes applications easier to prepare and process. Removing the condition that minor use extensions must be in the public interest and allowing applicants to rely on mutual recognition even when the reference use is not classified as minor reduces procedural complexity and cost. This increases the likelihood that companies, including SMEs, will apply for minor-use authorisations and should broaden availability of PPP for minor uses across the Union. For farmers, especially those growing high-value crops on limited surfaces such as certain fruits and berries, wider availability means more pest-management options. Better fit between products and needs can support improved crop protection and yields. The overall effect is a more predictable and attractive framework that expands market opportunities for applicants while strengthening pest-management choices for users.

Clarifying provisions related to treated seeds

Fragmented implementation of the existing provisions in the PPP Regulation related to treated seeds creates uncertainty about which rules apply to imported seeds treated with PPP not authorised in any Member State. There are divergent practices between Member States on what constitutes lawful sowing of treated seeds, e.g. whether the active substance must be approved in the EU; how to handle other propagating material such as tubers or seedlings; and who carries the compliance responsibility along the supply chain.

The proposal clarifies the situation by prohibiting the sowing in the EU of imported seeds treated with plant protection products that are not authorised in any Member State of the Union. It also clarifies that the rules on treated seeds apply to other plant reproductive material, including tubers, bulbs and seed potatoes. To avoid creating additional burden for farmers, machinery used solely for sowing treated seeds is excluded from the obligations applicable to pesticide application equipment under Directive 2009/128/EC on the sustainable use of pesticides.

These amendments will facilitate the free movement of treated seeds and improve their availability to farmers, irrespective of the Member State of use. They will strengthen controls on imports of treated seeds and help to minimise risks to human and animal health and the environment. The measure improves market fairness and availability for compliant treated seeds, with no extra obligations for farmers or industry.

Prioritising and simplifying authorisation for PPP to prevent establishment and spread of regulated pests

Failure to eradicate and/or prevent spread of pests regulated under the Plant Health Law (Regulation (EU) 2016/2031) carries very high economic and social costs.[37] For some crops, propagating material should be free of regulated pests or meet very low thresholds to safeguard production. If establishment or spread cannot be prevented, overall use of plant protection products is likely to increase over the medium or long term. National authorities responsible for

37 The JRC estimates production losses up to €32.5 billion for pine wood nematode, export losses up to €1.9 billion for *Spodoptera frugiperda*, and almost 300 000 jobs lost due to the effects of *Xylella fastidiosa*.

plant health need timely access to effective PPP uses to implement contingency plans. Professional users, including farmers and growers, face fewer options and slower access to needed tools. Applicants, in particular SMEs, encounter high administrative effort for small markets and limited prospects of recouping costs. Forestry and exporting plant propagating materials producers are exposed to higher risk and potential losses when effective pest control means are not available.

This proposal introduces a one-zone application for PPP used to control pests regulated under the Plant Health Law, replacing the current three-zone approach with a one-zone approach for these cases. In parallel, this omnibus will also prioritise such applications in the authorisation workflow. Together, these measures will provide for faster access to PPP to control pests regulated under the Plant Health Law and let the authorities act quickly and effectively.

Faster access to the market for PPP needed for the purposes of Regulation (EU) 2016/2031 will further support effective control. In the short term, Member State authorities and professional users, including farmers, benefit because they often need to act with urgency under national contingency plans. The one-zone approach reduces administrative costs, since applicants prepare and submit one interzonal application instead of three zonal applications.

Over the medium and long term, EU agriculture and forestry benefit because successful prevention avoids the significant additional costs that arise when regulated pests establish and spread. Applicants, in particular SMEs, benefit from simplified procedures that make small-scale applications more viable and should lead to more submissions for uses against regulated pests. For pests that affect forested areas, avoiding establishment and spread also maintains the resilience of EU forests and enhances their role as natural carbon sink.

Ensuring coherent data protection EU-wide

The current data-protection regime under Regulation (EC) No 1107/2009 is territorial by Member State and protection periods lack clear, uniform start and end dates. For the same test or study report, protection can begin and expire on different dates across the Union, especially when studies are used for renewals or for extensions of authorisations to minor uses. Competent authorities and applicants do not have a single, transparent reference point, which creates disputes and adds case-by-case administrative checks.

Misaligned timelines distort market entry. When protection still applies in the Member State of submission of an application for authorisation, follow-on applicants must assemble data-matching dossiers or negotiate letters of access, even if protection has already lapsed elsewhere. This delays authorisations, raises costs, and produces uneven availability and prices across the Union. Smaller markets are hit hardest, since originators may deprioritise submissions and SMEs struggle to recoup high entry costs on limited volumes. Farmers in these Member States face fewer options and slower access.

Systematic delays in renewals of PPP authorisations can prolong protection in practice. If a renewal runs late, studies remain protected for longer in that Member State, creating artificial extensions that block competitors from entering the market without adding safety. Because dates are not aligned Union-wide, these extensions occur unevenly and persist unpredictably.

Divergent national interpretations further increase workload and litigation risk. Determining whether a study is protected, for how long, and on what basis requires legal and technical checks

that differ across Member States. Time spent resolving protection status uncertainty reduces capacity for risk-relevant assessment work. For operators, uncertainty about protection status delays investment decisions and creates holding costs, which weigh most on SMEs.

Taken together, patched territorial protection, opaque timelines, extensions of protection due to delays in renewal procedures, and divergent practice weaken the internal market. They slow competitive entry for generic products and also for new products based on already approved active substances that rely on already approved active substances, fragment availability for farmers, and increased costs, while offering no improvement in protection standards.

This omnibus proposes to restore EU-wide data protection for test and study reports used in regulatory procedures for approval of active substances and authorisation of PPP, with clear starting and ending points that apply across all Member States, including for studies used in renewals and minor-use extensions.

EU-wide data protection will make the regime easier to apply, reduce administrative burden for competent authorities, and give applicants predictable timelines. It will facilitate access to the market for products based on already approved active substances, since protection will start and end at the same time in all Member States. Farmers should see more even availability of products at comparable costs regardless of where they are established.

Today, when data protection still applies in the Member State for which an application for authorisation is submitted, post-patent companies report that a data-matching dossier costs about EUR 5.15 million on average, compared with EUR 1.45 million when protection has expired, implying an additional EUR 3.7 million for obtaining authorisation for a PPP containing an active substance for which data are still protected. Lack of clarity and artificial data protection extensions caused by renewal delays cost around EUR 14.8 million per year across reporting post-patent companies.[38] Moving to an EU-wide regime will reduce these extra costs and associated delays, and savings can be reinvested in the development of new products, broadening the toolbox available to EU farmers.

The proposal preserves the purpose of data protection, which is to reward investment in generating studies for a limited period, while ensuring that protection does not extend beyond the statutory duration. By ending territorial fragmentation, it should also help SMEs enter smaller markets once protection expires across the Union at the same time, improving competition and choice for farmers.

Clarifying the provisions related to basic substances

Basic substances have a primary use outside agriculture but can be valuable for plant protection. Article 23 of the PPP regulation, which covers their placing on the market and use, is interpreted unevenly across the Union. Several Member States allow only “use” for plant protection purposes and do not allow placing on the market for purposes of plant protection, while others permit also their specific marketing for such purposes. This divergence creates legal uncertainty, unequal opportunities for farmers and amateur users, and difficulties in cross-border trade in products that

[38] For more detail on the cost saving calculations, view section 1 of Annex III on methodology.

are lawful in one Member State but regarded as illegal in another. Authorities face enforcement difficulties, and applicants receive inconsistent signals about what is required.

Key concepts are not applied consistently. The absence of EU-level clarity and a common approach to placing on the market, the presence of stabilisers for ensuring shelf-life, labelling and responsibilities along the supply chain leads to disputes and extra administrative work. The current exclusion of a "dual approval" (i.e. the same substance cannot be an approved basic substance and be marketed as part of an authorised PPP following an approval as regular active substance) creates uncertainty when an approved basic substance later obtains an approval as a regular active substance. Eligibility criteria such as "primary use for other purposes" and the handling of substances of concern are difficult to implement consistently. This omnibus clarifies what is allowed and streamlines how basic substances are approved and made available, while keeping requirements proportionate to their low-concern profile. More specifically, the proposal aims to

- clarify that basic substances may be placed on the market for plant protection purposes, in addition to being used for such purposes and that products containing basic substances may be labelled with clear information on plant protection purposes
- streamline applications and approvals by clarifying rules on substances of concern, primary use for other purposes.
- resolve "dual approval" uncertainties, so that a substance approved as basic retains that status even if later approved as a regular active substance.

These amendments streamline approvals and harmonise availability of basic substances across the Union. Users gain a level playing field and greater access to products that are useful for plant protection and will be labelled with clear information for correct use, as well as predictability that the status of a basic substance will not change, which improves planning and competitiveness. Clarifying eligibility and marketing conditions should increase the number of both applications and approvals, making basic substances more readily available to amateur and professional users.

Resolving the dual-approval issue protects the basic-substance status and its approved uses. Investments by public bodies, research organisations, farmer associations and SMEs, who are often the applicants for the approval of basic substances, are safeguarded, since approved basic substances uses remain valid even if the substance later receives a regular active substance approval. Co-existence of basic and regular approvals can stimulate innovation, because different formulations in PPP may enhance performance while farmers retain the option of using a simpler and often more affordable basic substance.

Public authorities, the Commission and applicants face less administrative burden as legal uncertainty and divergent national practices are removed.[39] For farmers and wider society, increased access to low-concern tools helps diversify the plant-protection toolbox, supports substitution of more hazardous substances, and aligns with integrated pest management.

Optional EFSA support to Rapporteur Member States

39 A quantified estimate of cost savings is not possible at this stage, due to limited data on producers, dossier costs and market effects, but the expected direction is lower compliance effort and fewer disputes.

Competent authorities in some Member States lack the complete specific technical and scientific expertise to complete their tasks as rapporteur Member State within the timelines of the PPP regulation. [40] This results in delays in drafting and updating assessment reports for approvals and renewals of approvals of active substances and creates avoidable back-and-forth exchanges with EFSA during the peer review process.

This omnibus would allow the RMS, to request optional, targeted technical support from EFSA when preparing the initial assessment report. Legal responsibilities, protection standards, and methodologies remain unchanged.

Faster resolution of technical questions shortens the time needed by the RMS and smoothen the peer review process. Greater methodological consistency raises the quality of draft assessment reports and reduces the need for rework during the peer review process. For Member States, targeted access to specialist expertise, helps smaller or capacity-constrained authorities meet deadlines without costly outsourcing, improves workload planning, and reduces the risk of divergent interpretations that later need correction. For operators, clearer and faster procedures mean more predictable timelines, fewer iterative data requests, lower holding and compliance costs, and earlier clarity on risk-management conditions, which is especially important for SMEs.

For farmers and the wider public, steadier regulatory throughput supports a reliable supply of approved tools while maintaining protection standards, lowers administrative burden through fewer procedural disputes, and improves transparency and trust through earlier convergence on methods and risk assessment outcome. The measure is expected to be resource-neutral for EFSA, with capacity for technical support of RMS created by efficiencies from shifting to unlimited approvals with targeted reviews (as described above), while any biocontrol-related resource needs are addressed separately (see section 3.1.1).

3.2.2. Simplification for biocidal products

The Commission Report on the implementation of the Biocidal Products Regulation (EU) No 528/2012 (BPR), adopted in June 2021, identified persistent problems in the functioning of the system, notably substantial delays in the approval of active substances, especially the review programme of existing active substances, and in product authorisations.[41] These delays also hinder the market entry of innovative active substances. In addition, concerns have recently been raised by Member States and economic operators about the expiry of data protection for all existing active substances at the end of 2025.

A comprehensive evaluation of the BPR has been launched in 2025 to assess the overall fitness of the regulatory framework. However, given the urgency of some of the issues identified, the Commission proposes to introduce a limited set of targeted amendments already now. These aim to alleviate the most pressing burdens, improve efficiency, and provide legal certainty, while leaving broader structural reforms to be considered as a follow up to the forthcoming evaluation.

Unlimited approvals with targeted renewals of active substances

The BPR requires that all active substances used in biocidal products undergo a thorough safety and efficacy assessment before they can be approved for use across the EU. To manage the

40 33rd Pesticide Steering Network meeting | EFSA
41 COM(2021) 287 final, SWD(2021) 128 final

transition from previously existing rules, the BPR maintained the review programme introduced by its predecessor (Directive 98/8/EC) for a systematic assessment of all existing active substances that were already on the market in 2000. This review programme has the objective to ensure that only substances meeting EU safety requirements remain available, thereby protecting human health, animal health and the environment, while supporting a well-functioning internal market for biocidal products. Pending the conclusion on an existing active substance, biocidal products containing it remain regulated under national rules of Member States, where such rules exist.

Under the BPR, the evaluations are carried out jointly: each application is assigned to a Member States authority acting as evaluating competent authority, which prepares an assessment report. The European Chemicals Agency (ECHA) then coordinates a peer review among Member States experts and helps ensure consistency of the system. Final decisions on approval of active substances are taken by the Commission in consultation with Member States representatives.

However, the review programme, launched in 2000, has been repeatedly extended and is now scheduled to end only by 2030. [42] [43][44] As of September 2025, just over half of the substance dossiers have been assessed. These delays adversely affect the BPR's core objective of ensuring that only substances meeting EU safety requirements remain on the market within predictable timelines. Most Member States authorities have not respected the deadlines for submitting their assessment reports. The 2021 implementation report identified several reasons for the persistent delay in completing the review programme.[45] Many national authorities face capacity constraints, lacking sufficient staff and expertise to process complex dossiers within the legal deadlines. Applicants themselves also contribute to delays, due to missing information in their initial applications, and the frequent submission of additional data requested during the assessment conducted by the evaluating Member State later than expected. Some dossiers are technically complex and raise scientific questions that must be resolved before an assessment can be finalised, requiring sometimes authorities to revisit or update earlier work. Frequent changes in technical guidance during ongoing evaluations, and inconsistencies in interpretation across Member States, have further slowed progress.[46] Finally, the adoption of new scientific criteria for the identification of endocrine-disrupting properties introduced in 2018, created further data requirements and assessment needs that added to the workload.[47]

Since 2015, the Commission has worked with Member States to accelerate the completion of the review programme through the expert group of Competent Authorities for Biocidal Products, with

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42 Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods (OJ L 262, 6.10.2009, p. 40).

43 Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances (OJ L 204, 31.7.2013, p. 25).

44 Commission Delegated Regulation (EU) 2024/1398 of 14 March 2024 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards a further extension of the duration of the work programme for the systematic examination of all existing biocidal active substances (OJ L, 2024/1398, 22.5.2024, ELI: http://data.europa.eu/eli/reg_del/2024/1398/oj).

45 These are detailed in COM(2021) 287 final and SWD(2021) 128 final.

46 Also indicated by stakeholders during the 2025 Implementation Dialogue: Implementation dialogue on Biocides - Public Health - European Commission, and referred in the AISE (2022), Assessment of the Biocidal Products Regulation (BPR) and its implementation, p. 15–16

47 Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1, ELI: http://data.europa.eu/eli/reg_del/2017/2100/oj).

stakeholders participating as observers.[48] These discussions led to agreements on several actions to accelerate the delivery of assessment reports for existing active substances.[49] In parallel, ECHA organised workshops and adopted an action plan on active substances. To provide more direct support, the Commission launched in 2023 a call for expressions of interest allowing Member States to apply for financial grants to strengthen their capacity under both the BPR and the PPP Regulations. As a result, nine Member States received a total of around EUR 6.8 million related to their tasks under the BPR.[50]

Despite these measures, by September 2025, only 51% of the review programme had been completed. This means that the safety of many active substances used in biocidal products on the EU market under transitional provisions has still not been established. This situation undermines policy objectives both by delaying full safety verification and by weakening internal-market consistency, since biocidal products remain in the meantime regulated under different national rules. At the same time, because approvals of active substances are time-limited, renewal procedures for substances already assessed and approved are ongoing, some even for a second cycle. These renewals consume significant resources in national authorities, diverting capacity away from the completion of pending assessments of existing active substances and further delaying the execution of the review programme.

At an Implementation Dialogue held on 15 July 2025, suppliers, formulators, and downstream users showed broad consensus on the need to reduce delays and improve predictability, which create a fragmented and uncertain regulatory environment.[51] Companies face uneven market access across Member States, long waiting times for active substance approvals and product authorisations that often exceed the legal timelines, delaying market access and distorting competition.[52] Such unpredictability directly affects the policy objectives of timely access to safe products and a level playing field for operators. This not only increases costs but also discourages innovation, as firms are less willing to invest in new solutions when regulatory processes are excessively long.[53]

Under the current system, approvals of active substances are granted for a limited period (usually 5–10 years) and must then be renewed. This creates a continuous cycle of renewal applications, even for substances that have already been thoroughly assessed and may not present new concerns. With this omnibus proposal, the Commission proposes to shift from systematic to targeted renewals. In practice, this means that:

- Approvals of most active substances would become unlimited in duration.
- Only substances of higher concern, i.e. those meeting the exclusion criteria (Article 5(1)) or substitution criteria (Article 10), and substances for which it has been decided

48 Register Code E03125 (Register of Commission expert groups and other similar entities)
49 Letters sent in 2015 and 2021 to responsible Ministers in all Member States to express her concerns about the delays in implementing the Biocidal Products Regulation (active substances assessments, product authorisations), and called on Member States to take action, including allocating sufficient resources; CA documents of CA-March18-Doc.5.1a - Final - Actions for AS review programme.pdf, CA-Dec23-Doc.5.4 - Final - Extension of RP beyond 2024.doc
50 *Contributing to more sustainable and circular food production systems by boosting Member States' capacities to evaluate and remove from the market unsafe pesticides and biocides – SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA*
51 Implementation dialogue on Biocides - Public Health - European Commission
52 VCI/FCIO (2021), *Joint Position on delays in the authorisation of biocidal products*
53 AISE (2022), *Assessment of the Biocidal Products Regulation (BPR) and its implementation*, p. 20 - 21

that their approval should be reviewed as a result of an earlier assessment, would continue to be subject to time-limited approvals.

To maintain a high level of protection for human, animal and environmental health, several safeguards will remain in place, including that all high-concern substances remain subject to periodic reassessment. Time limits could also still be set where justified by a risk assessment. The Commission, in cooperation with Member States experts, could periodically select substances for a full renewal or re-examination. Early reviews under Article 15 of the BPR would also remain possible where new evidence suggests a potential risk. These safeguards ensure that moving away from systematic renewals does not adversely affect the high level of human, animal and environmental protection required under the BPR.

The change would preserve all essential safety safeguards while significantly reducing the number of routine renewal procedures. This would free up resources in Member States and industry, allowing faster completion of the review programme and more timely product authorisations. By shifting capacity from systematic renewals to targeted assessments of substances more likely to present risks, the measure enhances the BPR's objectives of high protection, timely safety evaluations and a well-functioning internal market. Businesses and many Member States strongly support measures that prioritise completion of the review programme and simplify renewal procedures, while NGOs caution against modifying the BPR before the ongoing evaluation is finalised. For industry, the proposal is expected to generate substantial cost savings by removing the need for systematic renewal applications. The main cost component of a renewal application is the generation of data to support the dossier.[54] Although a renewal dossier may require fewer studies than a first approval, the potential savings are often offset by new obligations, such as updated testing requirements and decisions by evaluating Member States to conduct full evaluations. Based on the number of active substances approved as of 1 September 2025 and assuming that the changes to the legislation would be applied as from 2027, the estimated savings amount to around EUR 71.5 million per year.[55] These savings reflect avoided costs for data generation, fees payable to ECHA, and fees to Member States evaluating authorities.[56]

In addition to the direct costs of data generation, applicants would also avoid several ancillary expenditures. These include consultancy fees for the preparation of dossiers, which can represent a significant share of overall compliance costs, particularly for small and medium-sized enterprises. Applicants would also be relieved of the administrative burden of their involvement in renewal procedures that frequently extend over several years; in certain cases, renewals have remained under assessment since 2018. Furthermore, the measure would reduce the uncertainty borne by companies, such as delays in business planning or the need to adjust to changing approval conditions as a result of the outcome of a renewal procedure.

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[54] The cost of preparing an active substance dossier under the BPR is estimated at EUR 1,000,000 to EUR 2,500,000 for study data development, plus an additional EUR 300,000 to EUR 500,000 for dossier assembly and risk assessment, and EUR 200,000 to EUR 750,000 in regulatory fees, totalling approximately EUR 1.5 to EUR 4 million per dossier.

55 The estimates are indicative and rely on existing data, primarily the 2009 Impact Assessment for the BPR, (SEC(2009)774 final) updated with inflation, current ECHA fees, and the number of active substances approved. While renewal dossiers typically require less data than first approvals, this advantage is offset by new obligations such as testing for endocrine-disrupting properties. A more detailed quantification will be carried out in the context of the full BPR evaluation starting in 2025.

[56] For detailed calculations, view section 2 of Annex III on methodology.

Competent authorities in the Member States would equally benefit from a reduction in workload. Resources currently dedicated to renewal procedures could be reallocated to the completion of the review programme and the assessment of product authorisation applications. This reallocation would facilitate more timely decision-making on long-pending dossiers and reduce the indirect costs associated with delay and unpredictability, to the benefit of both public authorities and economic operators.

While these additional benefits are more difficult to quantify than the direct cost savings linked to dossier preparation, they are nevertheless significant. The avoided costs of data generation remain the primary driver of savings. However, when combined with the reductions in consultancy, administrative and business planning costs for applicants, and the efficiency gains for Member State authorities, the cumulative impact of the measure considerably strengthens its overall effectiveness and proportionality.

Removal of the obligation to publish Union authorisations in the Official Journal of the EU

The BPR allows companies to apply for a Union authorisation, which is valid under the same conditions in all Member States. At present, each Commission decision granting such an authorisation must be published in full in the Official Journal, including the Summary of Product Characteristics in all EU languages. This requirement is cumbersome and causes delays. It adds little value, since the complete decision is already available on the ECHA website.[57]

With this simplification package, the Commission intends to simplify how Union authorisation decisions are adopted and published. Today, each authorisation is issued via a Commission Implementing Regulation and published in full in the Official Journal. Under the new approach, Union authorisations would instead be granted via Commission Implementing Decisions, notified directly to the applicant. For transparency, only a summary of each decision would appear in the Official Journal, while the complete text would remain available on the ECHA website. This change brings the procedure into line with the way authorisation decisions are adopted and disseminated in other comparable regulatory frameworks, ensuring consistency across the Commission's decision-making practice.[58]

The proposed measure will simplify the publication procedure for Union authorisations and remove unnecessary administrative burdens. It will not affect the legal certainty of authorisation decisions or the objectives of the BPR, as transparency is maintained through summary publication in the Official Journal and full access to decisions on the ECHA website.

For companies, the main benefit is faster adoption and publication of Union authorisations, as well as amendments to Union authorisations. This will reduce costs linked to delays in placing products on the market in all Member States. The impact is particularly relevant for seasonal products such as insecticides or mosquito repellents, where even short delays can result in missed market opportunities. Although the cost savings cannot be precisely quantified, they are expected to be significant for operators. By shortening procedures, the measure increases predictability for businesses and improves efficiency for both authorities and applicants.

57 https://www.echa.europa.eu/information-on-chemicals/biocidal-products

58 For instance, authorisation decisions of substances adopted under REACH Regulation (EC) No 1906/2007, or authorisation decision of medicines for human or veterinary use adopted under Regulation (EC) No 726/2004

Article 95 data protection

Article 95(5) of Regulation (EU) No 528/2012 foresees that on 31 December 2025 protection expires for all data submitted for existing active substance/product-type combinations in the review programme but for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013 and which will still be under examination in the review programme after 31 December 2025. The protection period was set to expire 10 years after mandatory listing of active substance suppliers of existing active substances on a specific list maintained by the European Chemicals Agency (ECHA) that took effect on 1 September 2015 (the Article 95 list). The purpose was to guarantee a fair compensation period for review programme participants, considering also that, for most participants, their data had already been protected since 2004-2008 (the time of submission of most of the applications for approval in the review programme), while foreseeing the possibility for other economic operators to use freely the data as from the beginning of 2026 to access more easily the market and bring down costs for the producers of biocidal products who buy active substances from the suppliers – and hence ultimately for the users of the biocidal products.

However, several active substance suppliers and their representative organisations have repeatedly raised concerns that, in the light of the delays in the completion of the review programme, as described above, the expiry of all data protection needs to be reconsidered. Due to the persistent delays in the review programme as described above, many active substances will still be under examination after that date. At the July 2025 Implementation Dialogue, some review programme participants raised concerns that the looming expiry of data protection, combined with ongoing delays, would weaken incentives for data generation and potentially lead to withdrawal of applications. [59] Similar concerns have been echoed by Member State experts[60]. The issue is particularly acute for data on endocrine-disrupting properties as, following the adoption of Commission Delegated Regulation (EU) 2017/2100, new scientific criteria to identify endocrine disrupting properties are applicable since 7 June 2018, and new studies to assess substances against these criteria had to be generated — in many cases this is still ongoing — for substances still in the review programme. These studies would currently receive only a very short duration of protection or no protection, despite their high cost and scientific importance. In addition, other data had also to be generated and submitted due to the lack of quality of initial data submitted in the concerned applications and/or due the need to submit new data following the evolution of technical guidance or requirements.

Without adjustment, this situation risks discouraging further investment in data generation, leading to the potential withdrawal of applications altogether and eventually lack of active substances to combat negative effects on human health or materials. It could also weaken the functioning of the internal market by undermining fairness between suppliers who have borne the costs of generating new data and competitors who would be able to use those data freely.

With this proposal, the Commission intends to adjust the rules on data protection under Article 95(5) of the BPR. The cut-off date for the protection of data related to existing active substances, which were still under review in the review programme on 1 September 2013, should be reconsidered, striking a balance between the interests of review programme participants, on the one side, and the interests of alternative suppliers of active substance and applicants for product

59 Implementation dialogue on Biocides - Public Health - European Commission
60 CA-June25-Doc.7.10 - Point from NL on data protection.pdf,

authorisation, on the other side, taking also into account the original intentions of the expiry of data protection set out in Article 95(5) of Regulation (EU) No 528/2012. The balance in the various interests should be reflected in the scope of the active substances and data concerned by the extension of protection, as well as in the duration of protection.

It is therefore proposed to extend the protection period for all data for active substance/product-type combinations for which a decision on the approval had not been adopted in accordance with Article 89(1), third subparagraph, of Regulation (EU) No 528/2012 by 7 June 2018, date of entry into application of the scientific criteria to identify endocrine disrupting properties. To ensure a simple application of the new provision by all parties, the extension of protection covers all data without any distinction. The completion of the review programme of existing biocidal active substances has been extended until 31 December 2030. It is therefore proposed to extend the protection of the concerned data until the same date. This corresponds to a period of maximum 11.5 years for data generated since 7 June 2018, which is considered an appropriate period of protection during which participants in the review programme can obtain compensation for the costs of the generation of data required by evaluating Member States. While the period of protection will be shorter for data generated only in recent years, the proposed extension of protection will cover all data in the application, including data submitted since the submission of the applications which have already benefitted from a longer period of protection. Furthermore, the Commission will conduct a full evaluation of Regulation (EU) No 528/2012 in the course of 2026/2027, including its rules on data protection, which will provide a basis for the consideration of potential changes in the future.

This approach would safeguard the interests of review programme participants, while still allowing alternative suppliers and product authorisation applicants to gain access to the market, maintaining a balance between these different interests. The measure would not affect the objectives of the BPR. It would not lower the level of protection for human health, animal health or the environment, but would maintain a fair balance between data owners and other operators. The scope of the active substance and data concerned is clearly defined, which limits the measure to cases where fairness is at stake. No direct cost savings are expected for industry, since the data in question must in any case be generated and submitted to complete the assessment of the active substance, and for the assessment of endocrine-disrupting properties. However, data owners would benefit from the possibility of obtaining compensation from other interested companies through letters of access. Access to protected data may be granted to alternative suppliers of the same active substance, or to companies seeking product authorisations once the substance is approved. The terms of access could vary, ranging from financial compensation to free access when data owners also act as substance suppliers.

Most industry stakeholders and Member States favour extending data protection for substances still in the review programme, whereas some operators warn that changing rules now could create legal uncertainty and hamper competition. In the Impact Assessment performed in 2009 for the proposal of Regulation (EU) No 528/2012 revising the former Directive 98/8/EC, the cost of preparation of an application for approval of an active was estimated between EUR 3 to 5 million (based on a study performed in 2007). Although no specific figures are available on the average costs of generating data related to endocrine-disrupting properties, these studies are generally considered highly costly, particularly because they often involve vertebrate testing. The costs for the generation of new studies related to other elements of an application are highly variable, depending on the issue for which evaluating competent authorities have requested a new study. By ensuring an appropriate period of protection, the measure helps secure a fair return on these

investments and maintains incentives for data generation, which is essential for the scientific robustness of the review programme.

3.2.3. Maximum Residue Levels

Regulation (EC) No 396/2005 establishes harmonised maximum residue levels (MRLs) for pesticides in food and feed, based on EFSA risk assessments, with the dual objective of protecting consumer health and ensuring the smooth functioning of the internal market. The 2020 evaluation of the EU pesticides legislation confirmed that the Regulation is overall fit for purpose and continues to deliver a high level of protection, but it also highlighted areas where procedures are complex, burdensome or lack legal clarity. In line with these findings, four targeted adjustments are proposed to simplify implementation without lowering standards:

- Broader possibility for transitional measures when MRLs are lowered
- Unlimited validity for monitoring-based MRLs with targeted reviews
- Residues of certain hazardous pesticides not approved in the EU in imported products
- Terminology alignment (LOD → LOQ)

Many stakeholders support clearer transitional arrangements for lowered MRLs, whereas NGOs and some farmers call for stricter treatment of import tolerances for non-approved substances, and several third-country partners warn about trade disruptions. These changes respond directly to evaluation findings on legal clarity, proportionality and efficiency, while ensuring that consumer protection and the internal market remain fully safeguarded.

Broader possibility for the application of transitional measures

The MRL Regulation allows the continued marketing of food products placed on the market before the entry into force of new and lower MRLs, provided they complied with the applicable limits at the time of production or storage.[61] This possibility is excluded when the lowering of an MRL is the consequence of a potential health concern. In such cases, the newly established lower MRL applies immediately to all products on the market, including stocks that were legally compliant when produced. This situation often arises when long-standing MRLs are re-evaluated based on updated data requirements or revised exposure models. The absence of the possibility to grant transitional arrangements under these conditions creates disproportionate effects for operators.

The impact is most severe for products with a long shelf life and high unit value, such as for example wine, hops or oils, and certain nuts and dried berries. Producers face the obligation of withdrawing or destroying stock, leading to significant financial losses. At the same time, these rules drive unnecessary food waste, contrary to the Union's policy objectives on sustainability and food loss prevention. Stakeholders, such as for instance hops, olive oil, wine, tree nuts, berries and tea producers, have repeatedly raised this concern and requested amendments to ensure legal certainty in such cases. This omnibus amends the relevant provision in Regulation (EC) No 396/2005 to permit in principle the continued marketing of products that complied with the MRLs applicable at the time of production in all cases when new, lower, MRLs are introduced. To maintain the existing high level of consumer protection, a decision on whether or not such a

61 Article 49(2)

transitional measure is acceptable in a specific case will then be decided by risk managers on a case-by-case basis, taking all the relevant information into account.

Fresh products with short shelf lives, which account for the biggest share of dietary pesticide exposure, would remain on the market only for a very limited time (days in most cases) after the applicability of the lowered MRLs, while many long shelf-life products that are consumed in less amounts and are used frequently in processed products blended with other ingredients, could remain on the market until the end of their shelf-life. The adjustment therefore does not alter the overall objectives of the legislation in terms of the high level of protection for consumers. The amendment would provide farmers and food business operators with legal certainty that stocks produced in compliance with the rules in force at the time of production can in principle continue to be sold, except where a high level of consumer protection cannot be ensured. This would reduce unnecessary food waste by avoiding the destruction of products that remain safe but become non-compliant solely due to technical re-assessments. Economically, the change would prevent disproportionate losses for producers of long shelf-life products, being some of them high-value products such as wine, hops, oils, tea, coffee and certain nuts and berries. While precise figures are difficult to quantify at EU level, for some operators avoided costs can be significant.

Simplification on the procedure related to setting MRLs based on monitoring data and strengthened provisions for review of MRLs

Regulation (EC) No 396/2005 allows MRLs to be set based on monitoring data instead of residue trials.[62] This approach is used, for example, for substances that have long been withdrawn from use in plant protection products but still persist as environmental contaminants, for minor dietary components such as herbal infusions and honey, or in cases where residues remain detectable many years after last use.

At present, MRLs established based on monitoring data are limited in time and must be reviewed within a maximum of ten years. Periodic review is appropriate for substances where residue levels can be expected to decrease. However, for substances that have not been approved for several decades and now persist only as environmental contaminants, with residue levels shown to be stable over many years (e.g. DDT, dieldrin, aldrin, hexachlorobenzene, mercury), mandatory reviews at fixed intervals are disproportionate and impose unnecessary costs as no changes are expected.

This omnibus proposes that MRLs based on monitoring data should by default be permanent, while retaining the possibility of review at any time where new information warrants it. To this end, this proposal aims to clarify Article 43 of Regulation (EC) No 396/2005 to specify that the Commission may initiate a review at any moment, based on an EFSA risk assessment.

This approach preserves the high level of consumer protection, as no reduction in safety standards or changes to the functioning of the internal market are foreseen. It increases procedural efficiency by removing unnecessary reviews, while ensuring that MRLs can still be reassessed at any time if new evidence emerges. At the same time, it alleviates administrative burdens for food business operators and Member States without creating significant additional costs. The amendment also strengthens legal clarity by explicitly confirming that reviews remain possible whenever required.

62 Article 16

Residues of certain hazardous pesticides not approved in the EU in imported products

Regulation (EC) No 1107/2009 governs the approval of active substances used in plant protection products, implementing criteria that prevent approval for the use in the EU of the most hazardous pesticides for health and environmental reasons. Regulation (EC) No 396/2005 allows the setting of import tolerances and alignment with Codex standards for residues of pesticides not approved in the EU if they pose no risk to consumers. This means that substances not approved under Regulation (EC) No 1107/2009 due to their intrinsic properties may still be present in imported products, provided they comply with the MRL.

The Parliament[63], Council[64] and stakeholder groups[65] have highlighted the perceived difference in the level of protection between the PPP and MRL regulations and called for an alignment of production standards between imported and domestic products.

In the Vision for Agriculture and Food, the Commission announced to pursue a stronger alignment of production standards applied to imported products, notably on pesticides. To advance on this, the Commission has launched in November 2025 a study to prepare an impact assessment that will consider the impacts on the EU's competitive position and the international implications and, if appropriate, the Commission will propose amendments to the applicable legal framework. In the meantime Regulation (EC) No 396/2005 is amended to provide that, for substances that are not approved in the Union and that have certain particularly hazardous properties, MRLs that have been set based on good agricultural practices in third countries nor Codex maximum limits may be set at the limit of quantification (technical zero) if considered appropriate in the light of the outcome of an impact assessment.

Based on the scientific criteria listed in Regulation (EC) No 1107/2009[66], this concerns substances with mutagenic, carcinogenic, or reprotoxic properties as well as endocrine disruptors that may cause adverse effects in humans. In addition, this concerns substances that are persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT) substances, and very persistent and very bioaccumulative (vPvB) substances, as well as substances with endocrine disrupting properties that may cause adverse effect in non-target organisms. Persistent substances, by their very nature, resist degradation, resulting in prolonged presence in the environment. Their

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[63] See for instance European Parliament resolution of 18 September 2024 as regards maximum residue levels for benomyl, carbendazim and thiophanate-methyl in or on certain products; European Parliament resolution of 17 January 2024 as regards maximum residue levels for thiacloprid in or on certain products; European Parliament resolution of 14 December 2023 as regards maximum residue levels for tricyclazole in or on certain products.

[64] AGRIFISH Council 24 June 2025 on the alignment of production standards applied to imported products in terms of pesticide MRLs.

[65] The Eurobarometer surveys, conducted by the European Commission, consistently reveal strong public support for pesticide reduction and environmental protection: 2019 Eurobarometer: Food Safety in the EU(link is external), 2020 Eurobarometer: Making our food fit for the future(link is external) – new trends and challenges, 2022 Eurobarometer: Food Safety in the EU(link is external), 2024 Eurobarometer: Attitudes of Europeans towards the environment(link is external)A 2023 Ipsos survey confirmed the strong concerns EU citizens hold about the impacts of pesticides on their health and the environment: IPSOS Citizens Poll on Pesticides(link is external) The final report of the Conference for the Future of Europe(link is external) included the need for high environmental ambition in food production systems, and to drastically reduce pesticide use (2022).

67 Organisation for Economic Co-operation and Development (OECD). Guidance document for single laboratory validation of quantitative analytical methods - guidance used in support of pre- and post- registration data requirements for plant protection products and biocidal products. ENV/JM/MONO(2014)20.

accumulation poses a significant threat to ecosystems, endangering biodiversity, agricultural production and food security. Endocrine disruptors, similarly, interfere with the hormonal systems of living organisms, causing detrimental effects not only to individual species, including migratory species, but also to entire ecosystems across national boundaries. Therefore, these substances create environmental concerns of a global nature that have a connection with the territory of the Union. Where an appropriate evaluation by the European Food Safety Authority (EFSA) of the hazardous properties of the substance under Regulation (EC) No 1107/2009 is not available, the Commission may ask EFSA for an evaluation under Article 43 of Regulation (EC) No 396/2005.

In addition, the proposal replaces the term “import tolerance”, which is often misunderstood, with "MRL based on a Good Agricultural Practice implemented in a third country”.

The changes proposed will increase clarity for stakeholders and authorities in the MRL setting process. They will also slightly reduce human resource needs in EFSA and Member States’ authorities as lengthy unnecessary assessments will be avoided.

Alignment of “limit of determination” with “limit of quantification”

There is a terminological inconsistency between Regulation (EC) No 396/2005 and international laboratory standards.[67] The Regulation refers to the “limit of determination (LOD)” as the threshold for quantifying residues. In analytical practice, however, the correct term is the “limit of quantification (LOQ)”, meaning the lowest residue concentration that can be reliably measured and reported using validated control methods. The confusion arises because “LOD” is widely understood in laboratory science as “limit of detection”, which is a different and lower threshold. Using “LOD” in the Regulation therefore creates ambiguity and has led to misinterpretation by laboratories and food business operators, undermining legal clarity and consistency with international standards.

This omnibus amends the relevant provisions in Regulation (EC) No 396/2005 to harmonise the terminology to conform to the internationally recognised term "limit of quantification (LOQ)".

By aligning the Regulation with international terminology, the amendment removes ambiguity and ensures clarity for laboratories and food business operators. This improves legal certainty and facilitates compliance, without altering consumer protection standards or the functioning of the internal market. The change is purely terminological and therefore does not generate any costs for operators or authorities while generating savings from avoided problems due to different interpretations of the current terminology.

3.2.4. GMM fermentation

The use of fermentation processes to manufacture products is of growing importance in the food and feed sector and in the wider bioeconomy. Genetically modified micro-organisms (GMMs), such as genetically modified bacteria and yeasts, are commonly used in fermentation processes to

67 Organisation for Economic Co-operation and Development (OECD). Guidance document for single laboratory validation of quantitative analytical methods - guidance used in support of pre- and post- registration data requirements for plant protection products and biocidal products. ENV/JM/MONO(2014)20.
Codex Alimentarius. Guidelines on performance criteria for methods of analysis for the determination of pesticide residues in food and feed. CAC/GL 90-2017.

produce enzymes, amino acids, vitamins and other compounds used in food and feed production. Around 80 companies globally are active in this field, of which 32 based in Europe. Over 400 such fermentation products have been authorised in the last thirty years under sectoral EU legislation on food additives[68], feed additives[69] or novel foods[70], all of which require a pre-market safety assessment and authorisation.

Where viable GMMs are present in the final product, the product constitutes genetically modified food or feed under Regulation (EC) No 1829/2003 and is subject to that Regulation.[71] However, for many fermentation products, the GMM is only used as a production strain and removed before the product is placed on the market. Such products may contain residues of the production organism, as it is not always technically feasible to eliminate all traces. The GM food and feed regulation does not apply to food and feed produced 'with' a GMO, such as food and feed manufactured with the help of a genetically modified processing aid. However, uncertainties remain as to whether the presence of residues of the genetically modified production strain render the food or feed 'produced from a GMO' and subject to the Regulation. This creates significant legal uncertainty for food and feed business operators and enforcement authorities in the Member States.

This lack of clarity has in some cases led to the withdrawal of fermentation products from the market on grounds of alleged non-compliance with Regulation (EC) No 1829/2003. Such withdrawals generate economic losses for producers and downstream food and feed operators, and unnecessary expenditure for competent authorities. Over the last five years, 18 alerts have been issued through the Rapid Alert System for Food & Feed (RASFF) portal. The total value of a recall depends on the quantities on the market of the affected product and of food and feed in which this product was used that need to be recalled. For instance, the cost of internal testing and investigation during a recent recall was calculated by the operator concerned at 20k EUR, and legal and regulatory fees increased the cost by a further 50 k EUR .

In addition, indirect costs range from reputational damage, disruption of business relationships, and loss of client trust, all impossible to quantify. For start-ups and SMEs, a single recall can be business-ending. Finally, recalls entail administrative burden through delays in shipment clearance, back-and-forth enquiries between business operators and competent authorities, and temporary blocking of consignments, all of which add further costs to operators. Competent authorities also face costs when recalls are triggered, such as inspection, administrative follow-up, and legal procedures.

In such situation, operators may pursue GMO authorisations under Regulation (EC) No 1829/2003 to shield themselves from enforcement risks. The cost of a full GMO authorisation is documented for plants, with an average cost of EUR 13 million.[72] Industry considers that a GMO authorisation would deter innovation, especially considering the cost for authorisation under another framework (e.g. for feed additives product approval estimated at basic costs without target animal studies approx. 100.000 EUR). In addition, it considers a GMO authorisation, with an associated timeline

68 Regulation (EC) No 1333/2008 on food additives
69 Regulation (EC) No 1831/2003 on additives for use in animal nutrition
70 Regulation (EU) 2015/2283 on novel foods
71 Regulation (EC) No 1829/2003 on genetically modified food and feed
72 Study to support the impact assessment of legislation for plants produced by certain new genomic techniques, https://op.europa.eu/en/publication-detail/-/publication/f00cd313-1ae1-11ee-806b-01aa75ed71a1/language-en

of over 5 years, too long in a highly competitive commodity business and rapidly adapting market compared to approximately 2 years for a feed additive authorisation.

Both the European fermentation industry and various Member States have repeatedly called for legal clarification, particularly in view of recent advances in analytical testing that allow to detect now even minimal DNA residues. Without it, legal uncertainty and inconsistent enforcement are likely to persist and intensify as the sector expands and detection methods become more sensitive. Consequently, the EU in most cases is no longer the first-choice market for innovations in this field by start-ups and global companies, and investments are directed outside of the EU.

To address the situation, this omnibus would clarify Regulation (EC) No 1829/2003 by specifying that fermentation products obtained using GMMs only as production strain are not food and feed "produced from GMOs"[73], provided there is no presence in those products of those GMMs and that any residues thereof are limited to non-viable cells, are minimized through reasonable attempts to remove them in accordance with good manufacturing practice and have no technological effect on the food or the feed.

This clarification does not affect the need for a pre-market safety assessment and authorisation of the products concerned and only concerns the determination of the legal framework under which the safety assessment and authorisation must be obtained. Products such as feed additives, food additives, food enzymes and novel foods would continue to be assessed under their respective EU rules before they can be placed on the market. Likewise, genetically modified food and feed products that do contain viable GMMs would remain fully covered by Regulation (EC) No 1829/2003 and would continue to require pre-market authorisation and safety assessment under the GMO legislation.

The amendment will maintain the high level of protection for human, animal and environmental health established in EU food and feed law. Its purpose is not to weaken safety requirements but to provide clarity where the current rules are applied in different ways. Several Member States and industry stakeholders support clarifying that fermentation products containing no viable GMMs are not covered by Regulation (EC) No 1829/2003, while NGOs argue that all such products should undergo full GMO risk assessment and labelling.

Overall, this amendment is expected to accelerate the entry of valuable fermentation products onto the EU market. This will particularly benefit SMEs and innovative biotech companies developing new enzymes, vitamins, amino acids and other fermentation products, helping them to bring innovations to market with greater certainty. In turn, the clarification will strengthen the competitiveness of the EU bioeconomy in a rapidly expanding global market.

3.2.5. Feed additives

The 2024 evaluation of the Feed Additives (FA) Regulation (Regulation (EC) No 1831/2003) confirmed that the legislation continues to meet its core objectives: ensuring a high level of protection of human and animal health and the environment, safeguarding users' interests, and

73 Building on recital (16) of Regulation (EC) No 1829/2003 and the Commission Report on the implementation of Regulation (EC) No 1829/2003 of 25 October 2006 (COM(2006) 626 final), a clarification would be included in Regulation (EC) No 1829/2003 excluding from the definition of 'produced from GMOs' food and feed fermentation products obtained with GMMs under certain conditions.

supporting the functioning of the internal market.[74] At the same time, the evaluation identified several provisions whose implementation creates some complexity or administrative burden, without corresponding safety benefits. These issues primarily affect feed business operators, especially SMEs, but also the Member States, EFSA and the Commission, who are required to process and handle applications for authorisation of feed additives. Three main areas for simplification or clarification emerged from the evaluation and subsequent stakeholder feedback:

- Renewal of authorisations: the systematic 10-year renewal obligation is seen as too resource-intensive for both operators and authorities.
- Modification of existing authorisations: some of the current procedures are too burdensome, for example when changing an authorisation-holder, or could be improved in terms of clarity and coherence.
- Labelling requirements: the current obligation for physical labels on additives and premixtures does not reflect the potential of digital tools for non-safety information and is not fully coherent with the labelling rules for feed materials and compound feed.

The amendments proposed in this omnibus target these specific provisions to simplify procedures, reduce administrative or regulatory burden and costs, and improve legal clarity. As they do not alter the fundamental objectives of the Regulation, businesses and many public authorities support removing renewals and streamlining authorisation processes to reduce administrative burden and improve competitiveness, while emphasising that high safety standards must be maintained. Safeguards such as the possibility to modify, suspend or revoke authorisations at any time remain in place, and are even strengthened, to ensure that these standards are not compromised.

Renewal of authorisations

Under the FA Regulation, feed additives are authorised for a period of ten years, and a renewal dossier must be submitted to request a subsequent ten-year authorisation. The 2024 evaluation concluded that this requirement generates high administrative and financial costs for businesses, EFSA and national authorities.[75] Renewal procedures absorb resources that could otherwise be directed towards the development and assessment of novel additives or towards focusing on the assessment of higher-risk categories, e.g. coccidiostats and histomonostats. While renewals of authorisation are granted after confirmation of safety, they are rarely based on substantive changes in the assessment, meaning the considerable costs involved are not justified by corresponding health benefits. A screening made of the about 120 feed additives, other than coccidiostats and histomonostats, whose authorisation has been renewed until October 2025, showed that safety issues were identified in that context only once, leading to a restriction of use of the authorised additive. Based on that finding, imposing a requirement of systematic 10-year renewal process appears to be disproportionately burdensome, taking account of the significant administrative and financial costs incurred by that requirement.

For feed business operators, the requirement creates significant recurring costs and lengthy procedures, which weigh heavily on SMEs and may discourage market participation. Smaller firms may forgo maintaining authorisations or delay bringing new products to market, leading to

74 SWD(2024) 46 final.
75 SWD(2024) 46 final, pp. 30-31, 35-39, 43-44, 50, 58 and 60-61.

greater concentration of approvals among larger operators. For EFSA, Member State authorities and the Commission, the constant flow of renewal dossiers ties up scientific and administrative capacity, even where no new evidence is available, reducing their ability to focus on genuinely novel products or emerging risks. At a systemic level, the EU feed sector considers that this framework undermines its competitiveness compared with countries such as Japan, Argentina, China or, more recently, the United Kingdom, where authorisations are not time-limited or subject to lighter, risk-based renewal requirements[76]. Unless addressed, the current regime will continue to drain resources, create unnecessary delays, and reduce the availability of innovative additives in the EU market.

Stakeholder input consistently reinforces these findings. The public consultation and targeted survey conducted in support of the evaluation, and the feedback received in the context of the Call for Evidence, revealed that businesses perceive the 10-year renewal as overly burdensome. In their view, this process undermines competitiveness by eroding return on investment and delaying the market entry of innovative, otherwise safe additives. Several national authorities also acknowledged the need to improve efficiency of the authorisation system by reducing administrative costs, to encourage innovation by reviewing the 10-year authorisation period, and admitted the potential for simplification. Several public authorities who provided feedback in the context of the Call for Evidence showed support for a removal of the burdensome renewal obligation, favouring a more flexible risk-based approach.

The joint letter of 28 March 2024[77], co-signed by six major feed chain associations (FEFANA, FEFAC, FEDIAF, COPA-COGECA, FEAP and AnimalhealthEurope), warned that resource-intensive renewals risk depriving EU farmers and feed producers, particularly SMEs, of innovative solutions. It called for a shift towards a risk-based approach, allowing reassessment only when justified by new safety data. Subsequent exchanges, including a FEFANA event in June 2024[78] with broad participation from industry, academia, Member States and the Commission, confirmed consensus on the need to modernise the Regulation. Follow-up letters and bilateral meetings in 2024–2025 reiterated that systematic renewals are considered as disproportionate, may result in discontinuation of market availability and should be replaced by continuous monitoring with targeted reassessments, when necessary, in line with the regime in force under other sectorial legislation, such as food additives.

This view has also been echoed at political level. Certain Members of the European Parliament[79] have raised the issue in questions and bilateral contacts, requesting the Commission to propose a revision of the FA Regulation as soon as possible in order to remove regulatory burden, allowing to foster technical and scientific innovation and to ensure a more balanced and fairer competitive environment between operators acting in the EU and in third countries.

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[76] SWD(2024) 46 final, pp. 33 and 266-267 and subsequent stakeholder feedback referred to in this section of the Staff Working Document.
[77] Letter of 28 March 2024 addressed to Executive Vice-President Maroš Šefčovič (Ares(2024)2404843).
[78] FEFANA Event 'The role of specialty feed ingredients for sustainable feed and food production and the need for modernisation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition', Copenhagen, 20 June 2024.
[79] Letter of 6 March 2023 from the Chair of the Committee on Agriculture and Rural Development of the European Parliament, MEP Norbert Lins, addressed to Commissioner Stella Kyriakides (ref. Ares(2023)1608370). Letter of 11 March 2025 from MEP Markus Ferber, addressed to Commissioner Olivér Várhelyi (ref. Ares(2025)2168177).

This proposal would remove the requirement for the systematic 10-year renewal of authorisations for all feed additives, except for coccidiostats and histomonostats. This category of additives is maintained under time-limited authorisations given the antimicrobial nature and higher risk profile of those products. For all other additives, authorisations would remain valid without renewal, unless evidence emerges that calls their safety or efficacy into question, which would trigger a review of the authorisation concerned in accordance with the provisions of Article 13 of the FA Regulation which allows to modify, suspend or revoke authorisations at any time, based on a new EFSA evaluation performed either on its initiative or on request from the Commission or a Member State.

The policy objective pursued by the FA Regulation to ensure a high safety level of protection will be preserved, considering in particular:

- the general supervision obligation and monitoring requirements on authorisation-holders, including implementation of post-market monitoring required in authorisations granted before the proposed new rules,
- the EFSA's possible scientific reassessment of authorisations on its own initiative or on Member States' or Commission's request or upon submission of applications for modification of authorisations or for the authorisation of new uses of authorised feed additives, under Article 13 of the FA Regulation.

In view of a scientific reassessment of existing authorisations, the EFSA's powers should include the possibility of requesting information and data to applicants and authorisation-holders and the accomplishment of any relevant tasks provided by Regulation (EC) No 178/2002 of the European Parliament and of the Council[80], such as data collection, commissioning of scientific studies and use of information identified from monitoring of emerging risks.

Alternative measures to the option of authorisations unlimited in time, such as longer authorisation periods for some or all feed additives or different authorisation periods according to the type of additives, were not considered as satisfactory. There would be a lack of objective criteria to differentiate between additive categories or functional groups in terms of safety or efficacy. There could also be a risk of absence of applicants for the renewal of non-holder specific authorisations, where, after a very long authorisation period, the initial applicant might no longer exist, and other interested parties would not be aware of a lack of timely preparation of an application for authorisation renewal. That situation could possibly create a discontinuation of market availability in the EU as regards certain feed additives with non-holder specific authorisation, but considered as essential for animal health, such as vitamins, trace elements or amino acids.

The measure would directly benefit feed business operators, especially SMEs, by removing the need to prepare costly renewal dossiers. It would also relieve EFSA, the Commission, the EURL for Feed Additives (EURL-FA) and national authorities of the resource-intensive tasks associated with renewals. Indirectly, farmers and the feed sector will benefit from more predictable access to innovative additives, while the EU economy gains in competitiveness and investment attractiveness.

[80] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj.

Currently, preparing a renewal application entails substantial costs for feed additive businesses. These costs mainly relate to generating the required data (mostly safety studies for renewal dossiers), staff time for dossier preparation, and, since 2021, compliance with additional transparency obligations under Regulation (EU) 2019/1381 (Transparency Regulation). On average, the direct cost per renewal application was estimated at EUR 216,000 in 2019 and increased to EUR 294,433 in 2024, including an additional 14% in costs and ~33.5 extra staff days due to more stringent transparency requirements[81]. These costs apply broadly across the industry, with little difference between SMEs and larger companies. For smaller firms, however, the financial weight of renewal dossiers represents a proportionally greater barrier to market participation.

Based on projected renewal volumes between 2025 and 2034, assuming 751 applications in total, applicants would face cumulative costs exceeding EUR 220 million in renewal-related expenses. Removing the periodic renewal obligation would thus produce an average cost saving of EUR 22.1 million annually.[82] The amendment would also reduce uncertainty linked to pending renewal decisions, freeing resources that companies could reallocate to research, product development and market expansion, and strengthen the competitiveness of operators who carry out their activities in the EU compared with those established and active in third countries who often benefit from lighter or non-time limited authorisation regimes in force in those countries. Overall, abolishing these systematic renewals is expected to provide strong benefits for SMEs especially, as they are disproportionately affected by the recurring financial and administrative burden.

The removal of the renewal obligation would also deliver significant savings for public authorities involved in the authorisation process. Based on projected renewal volumes between 2025 and 2034, the cumulative cost of renewals for EU institutions and Member States would reach more than EUR 5 million annually, which could be redirected to higher-value activities such as the assessment of new feed additives or emerging risks [83]. Beyond direct budgetary savings, the measure would enhance efficiency and prioritisation within EFSA and national competent authorities, allowing scarce scientific expertise to be focused where it adds most value. It would also reduce the administrative burden associated with processing applications, and issues handled within the SCoPAFF meetings.

Modification of existing authorisations

The FA Regulation sets out procedures for modifying existing authorisations after the adoption of an EFSA opinion, either on the initiative of EFSA, on request of a Member State or of the Commission, or through the submission of an application by an authorisation-holder. In practice, some of these procedures are disproportionately heavy or could be improved in terms of clarity and coherence. In particular:

[81] Survey carried out in March 2024 by FEFANA among its members on the impact of the Transparency Regulation on the costs and processes faced when submitting applications for authorisation.
[82] For detailed calculations, view section 3 of Annex III on methodology.
[83] Average costs per renewal dossier, when adjusted to 2024 values, are estimated at €16,022 for the Commission, €4,424 for the EURL-FA, €36,079 for EFSA, and €16,958 for Member States. These figures reflect staff time, expert costs, and administrative resources devoted to processing renewals, including the additional transparency tasks introduced since 2021.

- Any change of the holder of an authorisation requires the adoption of a specific regulation. This creates unnecessary administrative burden and inefficient allocation of resources for all entities involved in the handling of these requests.
- There is no specific procedure for requesting a modification of non-holder specific authorisations. Operators wishing to introduce changes are therefore, in principle, required to submit a new comprehensive application dossier, which generates unnecessary costs. In practice, this gap has led companies to submit requests to the Commission, which has in some cases consulted EFSA on whether the existing authorisation continued to meet the safety and efficacy conditions after modification. This ad hoc approach has created some inconsistency and legal uncertainty.

The 2024 evaluation highlighted the burdensome or complex nature of the above-mentioned modification procedures. The processes of changing authorisation-holder and modifying non-holder specific authorisations were identified as particular areas for potential clarification and simplification[84]. These findings were echoed by stakeholders: in the consultations underpinning the evaluation, a majority of business respondents viewed these procedures as excessive and creating uncertainty. Industry associations such as FEFANA and FEFAC have since reiterated the need to remove legal uncertainties and non-safety related burdens which prevent business operators, in particular SMEs, to keep-up with regulatory and administrative demands[85]. Likewise, several national competent authorities noted that the administrative burden linked to modification requests can be reduced and called for simplification.

The proposal introduces a clear and simplified procedure for modifying existing authorisations for these recurrent cases:

- Change of authorisation-holder: this change would require a mere administrative notification, with an update to the Register of feed additives, without the need to adopt a dedicated regulation.

- Modification of non-holder specific authorisations: operators seeking to modify some terms of such authorisations, by expanding use conditions, would no longer need to resubmit full applications for a new authorisation or use an ‘indirect’ procedure via a request to the Commission, who might in turn possibly consult EFSA on a proposed modification. Instead, they will be able to submit a targeted modification request limited to the relevant data supporting the change.

These reforms deliver both administrative and financial savings. Removing the obligation to adopt a regulation for holder changes is estimated to avoid around EUR 320,440 in Commission staff costs over 2025–2034, with modest additional savings for Member States [86]. While limited financial impact on the costs incurred by industry, it will lighten administrative burden.

[84] SWD(2024) 46 final, pp. 30, 58-59, 235.
[85] Concerns expressed in particular in an e-mail of 4 December 2024 from FEFANA addressed to the Cabinet of Commissioner Olivér Várhelyi, referring to the joint letter of 28 March 2024 co-signed by six major feed chain associations (ref. Ares(2024)8662776).
[86] Based on the 13 such regulations adopted between 2015 and 2024, with average processing costs of **€16,022 per application (2024 prices)** for the Commission, there is an assumption for 20 holder changes in 2025 - 2034.

The proposed simplification and clarification of the modification procedures will be all the more necessary since, in the absence of a renewal obligation, these procedures will be more likely to be used. In particular, the proposed clarification on the modification of non-holder specific authorisations would enable smaller companies to adapt products and respond more flexibly to market opportunities, while preserving the high level of safety oversight for the modifications.

Beyond these gains, the simplifications bring greater legal certainty, speed and predictability, particularly during mergers, acquisitions or product portfolio adjustments. For public authorities, the reform reduces the time and resources spent on low-value administrative work, allowing expertise to be redirected to the assessment of genuinely novel products and emerging risks. These simplifications do not compromise policy objectives and do not weaken existing safeguards: any modification with potential safety implications will continue to undergo a full scientific evaluation by EFSA, thereby maintaining the high level of protection for human health, animal health, and the environment.

Digital labelling of non-safety related information

The 2024 evaluation of the FA Regulation found that the labelling provisions are generally effective in ensuring that safety information is available along the feed chain. However, it also concluded that greater coherence with the labelling rules for feed materials and compound feed under Regulation (EC) No 767/2009 would improve the system by allowing more flexibility, in particular through digital labelling[87]. The current obligation to display extensive information on the physical label, even when not safety-related, places a disproportionate burden on operators. SMEs are especially affected, as smaller batch sizes and less flexible stock management make them more vulnerable to packaging and labelling costs.

Stakeholders strongly echoed these findings: in the public consultation and targeted surveys underpinning the evaluation, most industry representatives stressed that current provisions are outdated and should be modernised to make them more practical, facilitating the information flow along the feed chain. In their joint letter of 28 March 2024, FEFANA, FEFAC, FEDIAF, COPA-COGECA, FEAP and AnimalhealthEurope also called for an urgent revision, describing the rules as excessively costly and not aligned with digital tools already used elsewhere. They highlighted three priorities: permitting digital labelling for non-safety information, simplifying communication through internationally recognised pictograms, and developing a voluntary EU Code of Good Labelling Practice to harmonise implementation and set rules for claims. Industry also urged that scientifically substantiated claims on secondary benefits of feed additives should be allowed, as in several non-EU jurisdictions. Member State authorities were more divided: many consider current costs justified to ensure safety, while others acknowledged that non-safety information could be handled more efficiently.

The proposal introduces greater flexibility in the labelling provisions of Regulation (EC) No 1831/2003, aligning them more closely with the framework for feed materials and compound feed under Regulation (EC) No 767/2009, in the sense that labelling by other means than a physical label will be allowed under certain conditions. In particular, the amendments would:

- allow the use of digital labelling for certain non-safety related information, under clear conditions ensuring accessibility and reliability;

[87] SWD(2024)46 final, pp. 44-45, 59.

- maintain the obligation to display all essential safety and use information on the physical label, so that users have immediate access;
- empower the Commission to adopt further rules to enhance and facilitate digital labelling.

The amendments preserve the core policy objective of ensuring safe use of feed additives. All safety-critical and essential-use information remains mandatory on the physical label. At the same time, operators will gain new flexibility to provide non-safety related information digitally. This change will reduce the cost of frequent label updates and enable clearer, more user-friendly communication along the feed chain.

In addition, the proposal clarifies the identification of the feed business operators who are responsible for the labelling of feed additives and premixtures of feed additives, to bring consistency with the general provisions of Regulation (EC) No 767/2009 regarding the labelling of feed.

The amendments are expected to deliver efficiency gains across the sector, with the greatest impact for producers of premixtures and SMEs active in several Member States. The 2024 evaluation estimated that annual labelling costs for premixture producers range from EUR 80,000 to EUR 223,000 per plant, covering translation, design, printing and label management.[88] While physical labels will still be required for safety information and a QR code, digital labelling will reduce the amount of text that must be printed and translated. Stakeholders highlight that the main benefits will stem from stock management, particularly for production aimed at the EU market (unified stock system) and shorter multilingual labels, thereby simplifying logistics.

Beyond direct cost reductions, the reform will generate operational efficiencies. Real-time updates will lower compliance risks and increase supply chain flexibility, and shorter labels will improve readability. Digital channels will also make it possible to provide more detailed product information than can be displayed on a physical label, under the conditions defined in the Regulation.

Because production models, labelling practices and stock management strategies differ widely across operators, a single EU-wide estimate of savings is not feasible. Nevertheless, the measure will enhance coherence with the rules for feed materials and compound feed, as well as with other EU legislation such as fertilising products, where digital labelling is already foreseen. It will also contribute to broader EU policy objectives on digitalisation, burden reduction and competitiveness.

3.2.6. Overlap in notification of national hygiene measures

Member States must notify draft national hygiene measures under two different legal frameworks depending on the type of measures: the Hygiene Regulations (Regulations (EC) Nos 852/2004 and 853/2004) and Directive (EU) 2015/1535 (TRIS database). This creates overlapping notifications and uncertainty about which procedure applies in each case. Competent authorities in Member States, as well as the Commission, end up applying the wrong procedure or providing duplicative notifications. Around 50 draft national hygiene measures are notified per year under

[88] SWD(2024)46 final, p. 36.

the Hygiene Regulations, with each notification inducing staff costs equivalent to roughly three weeks of a full-time post in both the notifying Member State and the Commission. Feedback from Member States indicates that distinguishing which parts of national measures fall under which procedure is not always straightforward. In addition, Regulation (EU) 2017/625 has replaced the specific notification procedure laid down in Regulation (EC) No 854/2004 on official controls of products of animal origin by the procedure provided for in Directive (EU) 2015/1535. The proposed amendment will therefore lead to more coherent rules.

The proposal amends the Hygiene Regulations to require that national measures be notified only under Directive (EU) 2015/1535. This aligns hygiene notifications with the existing general notification procedure. As a result, Member States will only use a single, harmonised procedure; the Commission will receive notifications through one channel; and all stakeholders will have access to them via the TRIS database. The general notification procedure ensures transparency, provides translation into all EU languages, and allows for peer scrutiny by all Member States. Streamlining the system reduces administrative burden without reducing the substantive safeguards in place.

Member State authorities and the Commission will benefit most directly from reduced duplication or misuse. Based on ~50 notifications per year, simplification could reduce notifications by 25–50%, leading to savings of several FTE for both MS and the Commission. Overall, Member States generally welcome simplifying these notification procedures, seeing it as a proportionate improvement that supports transparency and subsidiarity.

3.3. Reducing unnecessary complexity in risk management

3.3.1. Depopulation reporting

The objective of Regulation (EC) No 1099/2009 is to protect animals at the time of killing. The Regulation also requires Member States to submit a specific annual report on depopulation operations.[89] In addition, Member States provide annual compliance reports under the Official Controls Regulation (OCR), which also cover animal welfare during killing, including during depopulation activities. These compliance reports are sufficient to ensure that the objective of Regulation (EC) No 1099/2009 is met.

In practice, the added reporting has proven of limited value. Several Member States do not submit depopulation reports at all, and where they are submitted the information is often incomplete, lacks analysis and is difficult to compare across countries.[90] In their replies to a Commission questionnaire in April 2025, nine Member States shared their views and experiences; three explicitly highlighted problems with the current system, including inconsistent definitions, incoherent reporting practices, and duplication with the OCR. Maintaining a separate reporting form on the DG SANTE Data Collection Platform also requires time and resources from both

89 Article 18(4)

90 For 2024, only six Member States provided the Commission with the required information regarding their depopulation activities through the intended DG SANTE data collected platform (compared to nine Member States in 2022 and 2023). An additional six Member States included similar information about depopulation activities in their 2024 annual reports under the Official Controls Regulation.

Member States and the Commission, without delivering meaningful additional benefits for risk management.

To address this duplication, this proposal removes the obligation in Article 18(4) of Regulation (EC) No 1099/2009 for Member States to submit a separate annual report on depopulation operations. Information on compliance with animal welfare requirements during depopulation activities will instead continue to be reported through the existing OCR annual reports. This streamlining ensures that relevant data remain available while consolidating reporting into a single framework that is more consistent and better suited to comparative analysis.

Removing the depopulation reporting obligation will reduce unnecessary administrative work for Member State authorities and free up resources for more targeted enforcement activities. It will also eliminate the need for the Commission to maintain and support a separate reporting tool, bringing efficiency gains on both sides. By consolidating reporting within the OCR framework, the information available will be more coherent and comparable, while safeguards for monitoring animal welfare at the time of killing remain fully in place. Overall, Member States appear to favour simplifying and integrating depopulation reporting into existing official-controls reporting, citing double reporting and inconsistent definitions as current problems.

3.3.2. Record-keeping for livestock farmers

Directive 98/58/EC requires farmers to keep records of medicinal treatments and animal mortalities.[91] Yet these obligations are covered in greater detail under Regulation (EU) 2019/6 on veterinary medicinal products[92] and Regulation (EU) 2016/429 on animal health[93]. The coexistence of parallel requirements leads to duplication for farmers and complicates compliance checks for national authorities.

While the potential for further simplification for farmers in general will be considered in the process of modernising EU animal welfare legislation under the *Vision for Agriculture and Food*, this proposal already deletes the overlapping provisions from Directive 98/58/EC.[94] This will consolidate record-keeping obligations under sectoral legislation, simplify compliance for farmers and ensure a clearer legal basis for enforcement. National authorities and the Commission will benefit from a more streamlined and coherent framework, while safeguards for animal health and welfare remain in place.

3.3.3. Updating BSE rules

Regulation (EC) No 999/2001 on transmissible spongiform encephalopathies (TSEs) is outdated and disproportionate to the current level of risk. It is no longer aligned with the latest scientific advice or with the international standards of the World Organisation for Animal Health (WOAH). Adopted at the height of the bovine spongiform encephalopathy (BSE) epidemic, when strict precautionary measures were justified, the framework has not adapted to the evolving epidemiological situation. Surveillance obligations, the list of specified risk materials (SRM) and

91 *points 5 and 6 of the Annex to Directive 98/58/EC*
92 *Article 108 of Regulation (EU) 2019/6*
93 *Articles 102(1)(d) and 186(1)(d) of Regulation (EU) 2016/429*
94 https://agriculture.ec.europa.eu/overview-vision-agriculture-food/vision-agriculture-and-food_en

trade restrictions on certain commodities remain in place, even though they are now excessive and scientifically unjustified.

The problem has become more acute since the adoption of the revised WOAH Chapter on BSE[95] in 2023 and EFSA's opinion confirming negligible risks from gelatine and collagen derived from bovine bones[96]. These inconsistencies have been repeatedly flagged by stakeholders and Member States in formal fora such as the PAFF Committee, the Chief Veterinary Officers' meeting, the Animal Health Advisory Committee and the EU TSE Working Group. The ongoing evaluation of the Animal Health Law (AHL) also finds that excluding TSEs from its categorisation process creates confusion, hinders prioritisation and leads to inefficient allocation of resources. Industry- and most authorities support alignment with updated WOAH standards and clearer, risk-proportionate rules, while a minority warn that simplification must not dilute strict BSE/TSE protections.

This situation imposes heavy and disproportionate burdens on both operators and competent authorities. For operators, the mandatory removal and destruction of materials that no longer pose a risk generates substantial regulatory and financial costs. Safe material is treated as waste, preventing its reuse in higher-value applications and running counter to the objectives of the circular economy. For competent authorities, large amounts of financial and human resources are tied up in monitoring and enforcement tasks that no longer reflect the actual level of risk. This diverts attention away from higher-priority animal health challenges where surveillance and enforcement would be more effective.

At EU level, partial misalignment with WOAH standards creates challenges for the EU operators in global markets. Unless the framework is revised, outdated provisions will continue to drive disproportionate measures, misallocate resources and generate inconsistencies, with millions being spent each year on controls that no longer add value. Against this background, Member States and industry both call for a science-based revision. They strongly support a modernised framework that simplifies surveillance, rationalises SRM disposal and removes outdated and unjustified trade restrictions, while safeguarding human and animal health.

The revision of Regulation (EC) No 999/2001 will modernise the provisions on BSE surveillance, the list of SRM, and trade restrictions on gelatine and collagen from ruminant bones.[97] Instead of prescribing rigid technical requirements in the basic act, the framework will be streamlined to allow these provisions to be updated more flexibly in line with new EFSA assessments and WOAH standards, using the regulatory procedures provided under Article 24. This will keep the TSE framework scientifically robust and internationally consistent, while maintaining a high level of protection of human and animal health, reducing disproportionate burdens, strengthening EU credibility, and allowing resources to be redirected towards higher-risk priorities in line with proportionality and the circular economy.

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95 World Organisation for Animal Health (WOAH), *Terrestrial Animal Health Code*, Chapter 11.4 Codes and Manuals - WOAH - World Organisation for Animal Health

96 EEFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2020. Scientific opinion on the potential BSE risk posed by the use of ruminant collagen and gelatine in feed for non-ruminant farmed animals. *EFSA Journal*, 18(10), e06267

97 Specifically, amendments will concern **Article 6**, **Article 8** and **Article 16**, together with consequential adjustments to other provisions to ensure coherence and consistency across the Regulation, as well as timely updates within the annexes.

The proposed amendments will deliver significant benefits across the food chain and for public authorities. Food business operators, including around 10,000 slaughterhouses and cutting plants across the EU, as well as many SMEs in the food and by-product processing sector, will benefit from lower disposal costs through a revised SRM list, fewer regulatory obligations and wider opportunities for trade. Each year, around 490,000 tonnes of bovine material are treated as Category 1, including SRM from slaughtered cattle and from fallen stock. With the proposed revision, a substantial share could be reclassified and channelled into renewable fuels, biogas and other higher value uses instead of being destroyed at high cost. More than 3.7 million livestock farmers and EU exporters will gain from clearer, risk-based rules for BSE control, which strengthen the EU's credibility on international markets and support smoother market access. For competent authorities, streamlined surveillance requirements and simplified SRM controls will reduce workload and free up resources for higher-risk animal health priorities. At EU level, the Commission will benefit from a clearer and more proportionate legal framework for disease control, ensuring consistency across Member States.

Alignment of BSE surveillance requirements with WOAH standards is expected to save approximately EUR 8.5 million annually for national authorities, with an additional EUR 3 million in indirect savings from reduced sampling, transport and laboratory workload.[9899] Operators will also benefit from lower on-farm sampling and logistics requirements, faster slaughter line speed, and reduced costs linked to cold storage carcasses until test results are available, though these savings vary between Member States and are more difficult to quantify. At EU level, EUR 1.55 million will be saved under the co-financed TSE activities of the Single Market Programme or future equivalents.

Updating the SRM list to reflect negligible BSE risk status could reduce about 445,000 tonnes per year of material that would no longer require to be treated as Category 1 and could be reclassified. This would generate EUR 132 million per year in disposal cost savings, with. around EUR 92 million benefiting operators and EUR 40 million benefiting administrations through reduced supervision and enforcement.[100]

Beyond cost savings, the revision will modernise the legal framework, making it more responsive to new scientific advice and international standards. It will reduce waste by enabling safe materials to be reclassified and processed under more economical rules, promote the recovery of materials for higher value uses that support the circular economy, and strengthen the EU's credibility in international fora. Crucially, these benefits will be achieved while maintaining a high level of protection for human and animal health.

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[98] For detailed calculations, view section 4 of the Annex III on methodology.

99 Calculations are based on EFSA's TSE Surveillance Report (2023) and Commission unit cost rates. For surveillance, the assumption of a 65% reduction corresponds to alignment with WOAH risk-based testing standards, applied to 922,841 annual tests at €12.83/test. Indirect savings include reduced sampling, transport and laboratory workload, and operational efficiencies for operators such as shorter carcass holding times and faster slaughterline, depending on national arrangements.

100 The assumption of a 40% reduction reflects partial alignment with WOAH Chapter 11.4. This involves reclassifying 196,000 tonnes per year of material consisting of SRM from healthy bovines slaughtered in Member States with negligible BSE risk and ~80% of fallen stock to be reclassified from Category 1 to another Category. This would result in disposal savings and avoid the incineration costs of ~€275/tonne, through increased recovery of renewable materials. The 40% alignment scenario reflects a plausible level of regulatory adjustment based on the expected outcome of ongoing scientific assessments, while maintaining certain precautionary elements of the current framework.

3.3.4. Flexibility in official controls

Targeted amendments to Regulation (EU) 2017/625 are proposed in two areas. First, to create a legal basis for partial clearance of consignments of plants and plant products at border control posts (BCPs). Second, to introduce limited derogations from accreditation requirements for reference laboratories.

Both changes are intended to reduce procedural burden for operators and competent authorities. In the case of BCPs, the current rules do not permit release of compliant parts of consignments when other parts are still under examination, creating delays and costs for perishable goods. In the case of laboratories, the current requirements to accredit all methods, for all possible contaminants, pests and matrices impose very high costs on those laboratories, as noted repeatedly by Member States and the Joint Research Centre of the European Commission (JRC). The amendments will not alter the objectives of the OCR.[101] They will provide flexibility in implementation while maintaining high standards of official controls.

Partial clearance of consignments of plants and plant products

Compliant parts of a consignment may not be released when other parts still require checks. In the particular case of phytosanitary certificates which cover very diverse lots, all products are held until all controls are completed. This affects importers of perishable goods, who face delays and potential spoilage on the one hand; and competent authorities who need legal provisions more tailored to the complexity of official controls. In certain instances, the data registered in TRACES system show that the delay in obtaining laboratory results may exceed one month, a timeframe that is more than sufficient to render perishable goods unsalvageable.

The issue results from Art. 50(3) of the OCR, which means that a single decision is taken per consignment. Importers and MS authorities have repeatedly raised the lack of flexibility, particularly during meetings of the Plant Health section of the Standing Committee on Plants, Animals, Food and Feed, and of the Working Party of Chief Plant Health Officers (COPHs) at the Council.

A targeted amendment would allow for partial clearance of consignments of plants and plant products at BCPs. This would enable competent authorities to issue clearance decisions for the compliant lots of a consignment, while retaining the non-compliant or pending-decision lots for further checks. The change would not affect the level of phytosanitary protection, as non-compliant lots would continue to be retained or rejected. Rather, it would make the implementation of OCR more proportionate and efficient for competent authorities, where BCP would gain from simplified procedures.

The proposed amendment would also bring significant benefits for operators. Importers of perishable products would avoid losses linked to the unnecessary detention of compliant goods. For example, in 2023, the competent authorities of the Netherlands reported that 2 965 consignments of perishable goods were subject to laboratory sampling, of which 1 198 were

101 Amendments are limited to Articles 50(3), 93 and 100 of Regulation (EU) 2017/625.

sampled only for parts of consignments. In 1 073 of these cases the consignments were ultimately compliant but were nevertheless detained until all checks were finalised. Extrapolating the Dutch data[102] to the EU as a whole suggests that around 4 160 consignments are unnecessarily delayed each year. With imports of fruit and vegetables valued at EUR 27.8 billion in 2023[103], the average value per consignment is approximately EUR 35 070. This implies potential avoidable losses of around EUR 146 million annually for fruit and vegetables alone. Considering other perishable products such as cut flowers, the total value of avoided losses may exceed EUR 150 million per year. Updated data from 2024 confirm that import values in these categories continue to increase, suggesting even higher potential savings.[104]

In addition to the quantified savings, the amendment would ease administrative pressure on border authorities and make procedures more predictable for operators. By reducing unnecessary detentions, it would also limit food waste and strengthen confidence in the functioning of border controls. Operators and Member States strongly support allowing partial clearance of consignments to reduce spoilage and delays, provided implementation is harmonised and control procedures remain robust. Overall, the measure would align implementation of the OCR more closely with its objectives: ensuring a high level of phytosanitary protection while keeping procedures efficient.

Accreditation of laboratories

The requirement for laboratories to obtain accreditation for the methods they use has created significant challenges, particularly in plant health, food contact materials (FCM) and feed additives (FA).[105] Laboratories are expected to seek accreditation for a very large number of contaminants, pests, matrices and methods, including those for which reference material is not available or which are only rarely applied.[106] This obligation affects in particular all relevant European Union reference laboratories (EURLs) and the 196 national reference laboratories (NRLs), including technical units within those laboratories, operating across Member States.

Compliance requires extensive preparation, repeated audits, and ongoing administrative work, drawing heavily on limited human resources. Laboratory experts are diverted from diagnostic and surveillance tasks to manage accreditation procedures. As a result, il is very difficult for reference laboratories to meet the requirements. This problem has been repeatedly flagged by Member States and by EURLs, such as the those for food contact materials and feed additives hosted by the JRC, who underline that the current framework does not sufficiently take into account operational realities.[107]

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102 Collected from European Commission: Directorate-General for Health and Food Safety, *TRACES – 2023 annual report*, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2875/231566

103 *DG AGRI, chapter 6,7,8 in table 'Evolution of Agri-food imports from Extra EU27, 2020 – 2024, page 8*

104 For detailed calculations, view section 5,1 of Annex III on methodology.

105 Articles 93 and 100 of Regulation (EU) 2017/625

106 The total accreditation burden depends on several parameters: the number of pests covered (more than 500 Union quarantine pests, of which 20 are designated as priority pests), the number of sample types ("matrices") for which tests must be validated (e.g. leaves, roots, soil), and the number of recognised diagnostic methods per pest.

107 For example, during several meetings of the Plant Health section of the Standing Committee on Plants, Animals, Food and Feed, and COPHs meetings, and EURL Directors meeting in October 2022

This proposal amends Regulation (EU) 2017/625 to allow targeted derogations from the requirement of mandatory accreditation for all the methods reference laboratories use. It is also proposed to allow derogations from the requirements to operate and be accredited in accordance with standard EN ISO/IEC 17025. While accreditation will remain in place for priority pests, feed additives, food contact materials and routinely used methods, where it is both feasible and proportionate, this change avoids laboratories devoting substantial resources to procedures that cannot realistically be fulfilled and resolves the current structural non-compliance.

This amendment will generate substantial cost savings. COFRAC (Comité Français d'accréditation) data shows that accreditation of a single technical unit of an NRL for two methods costs around EUR 68 000 over five years.[108] Applied to the 142 technical units covered by the 27 plant health NRLs, while assuming accreditation of an initial batch of 50 quarantine pests prioritised per unit, among more than 500 quarantine pests, and considering a minimum of three different plant matrices, this results in a potential burden of around EUR 290 million annually.[109]

In the plant health area, the amendment would avoid that all 142 technical units should be accredited for numerous pests, but only for one pest per main group of pests (bacteria, insects, fungi, nematodes or viruses) and per method. If a technical unit is accredited for one method for one bacterium, the amendment grants accreditation with the same method for all bacteria. Considering the cost for one of pest, 2 methods and three matrices, the estimated cost for the 142 technical units would amount to EUR 5.8 million annually. This corresponds to a cost saving of EUR 478million annually.

For feed additives and food contact materials, data of the Belgian Accreditation Body (BELAC) indicate that accrediting a laboratory for two methods over five years costs around EUR 35,500, equivalent to EUR 3,550 per method per year. Applied to 54 NRLs and two EURLs, and assuming 600 methods per laboratory, this translates into an annual fee burden of about EUR 119 million. Accreditation also entails staff costs. Preparing documentation and undergoing audits requires 2 to 4 person-months per method, equivalent to EUR 12,000–56,000 over five years. Using a mid-point of EUR 6,800 per method per year, the EU-wide staff burden amounts to roughly EUR 19 million annually. The combined baseline cost of compliance for FA and FCM accreditation is therefore close to EUR 138 million per year.

Applying the same family-based logic as in plant health, laboratories would need to maintain accreditation for about five representative method families, rather than 600 individual methods. This reduces the accredited scope to around 10% of the baseline, leaving a residual cost of about EUR 13.8 million per year and generating savings of approximately EUR 124 million annually.

In addition to the quantified savings, the amendment delivers legal certainty for laboratories and competent authorities through clearer, more proportionate requirements. Many stakeholders, including Member State laboratories, support more flexibility on accreditation for certain methods, seeing current requirements as disproportionate, while stressing that the general quality-assurance framework should remain intact. Staff resources can be redirected from lengthy

108 Comité Français d'accréditation represents the French Committee for accreditation and is the reference body in France for accreditation, unit cost based on data for a medium-size laboratory with one technical section. Costs include instruction fees, evaluation fees, audit logistics, extension fees and annual licence fees over a 5-year accreditation cycle.

109 For detailed calculations, view section 5,2 of Annex III on methodology.

accreditation exercises to core diagnostic and surveillance work, strengthening the Union's preparedness for plant health and food safety challenges.

4. CONCLUSION

This Staff Working Document consolidates the analysis underpinning the food and feed safety simplification omnibus. The omnibus provides for a focused set of adjustments to streamline procedures and clarify rules, while maintaining a high level of protection for human, animal and environmental health. Intervention is limited to areas where recurrent administrative costs and avoidable delays are most pronounced, notably systematic renewals, without altering core safety standards. In other words, these "quick fixes" do not affect the underlying safety objectives: all review, withdrawal and risk-management powers remain fully available to act on new scientific evidence and implementation experience.

The expected effects are reduced administrative workload for economic operators, faster and simpler decision making by competent authorities, official controls with fewer bottlenecks, and greater legal certainty through the removal of grey zones and duplications. Administrative capacity can be reallocated to higher-risk files and to the assessment of new science and innovations. Overall, safeguards remain intact across the sectoral legislation and key definitions are clarified to support consistent implementation. Science-based risk assessment continues to anchor decision-making.

The implementation of the proposed measures will take place in two phases reflecting their technical complexity and the adaptation time needed by administrations and operators. Most measures, covering biocontrol PPP, biocides, feed additives, etc. will start producing tangible benefits already from 2027 onwards. By contrast, the simplification of the wider PPP framework, which entails structural changes to renewal and authorisation procedures, will require a longer transition period.

For businesses, these measures are estimated to deliver overall annual cost savings of EUR 335 million from 2027, rising to EUR 428 million annually from 2029 once the PPP simplification becomes operational. In this mandate, these twelve simplification measures will therefore amount to at least EUR 1 billion between 2027 and 2029, and a further EUR 2.1 billion of cost savings for business are expected in the following mandate.

For national and EU administrations, the gains are equally significant. The simplification measures are expected to reduce administrative costs by about EUR 661 million per year, reflecting freed capacity in national competent authorities, EFSA and the Commission. This corresponds to a cumulative reduction of around EUR 3.3 billion in administrative costs between 2027 and 2034.

Following adoption, practical implementation support will be provided where useful, for example through harmonised guidance. Stakeholder input on future simplification opportunities will continue notably via the European Board on Agriculture on Food, the usual feedback channels and structured exchanges with the European Commission and competent authorities. Insights from implementation and monitoring will be part of the regular stress-testing exercise and inform any subsequent proposals.

ANNEX I: SUMMARY OF COST-SAVINGS

Measure	Businesses (EUR/year)	SMEs (EUR/year)	National & EU administrations (EUR/year)	Type of cost saving
Aerial spraying of PPP	Moderate savings from more efficient PPP application, i.e. reduced labour needs, easier access in difficult terrain, lower fuel & logistics costs, and potential lower PPP use through more precise application. Scale depends on MS uptake.	Small–moderate gains where labour / access constraints bind	Small efficiency gains in permitting and regulatory oversight.	Recurrent adjustment cost savings.
PPP simplification, including biocontrol	22 million due to provisional authorisations of biocontrol PPP: reduced dossier preparation and consultancy needs 6.5 million for unlimited approval of biocontrol active substances: avoided renewals, avoided data-generation cycles 49.6 million for unlimited approval of most active substances: removal of systematic renewal costs,	Substantial benefit, especially in regard to biocontrol PPP, but no robust EU-wide split feasible.	Small–moderate admin time saving	Recurrent administrative cost savings.

	including studies, fees and expert support 14.8 million for amended provisions on data protection: reduced preparation of supporting studies and lower cost of navigating data-sharing obligations			
Biocides	71.5 million in recurrent administrative savings from the elimination of routine renewal dossiers, reduced need for new studies, lower consultancy expenditure and lower fees.	High relative gain for SME formulators.	Small–moderate admin saving.	Recurrent administrative cost savings.
MRLs	Small to moderate savings from fewer MRL adjustment requests and avoided write-offs respectively.	Small–moderate savings for SME traders.	Minor case-handling efficiency.	Recurrent administrative + adjustment cost savings.
GMM fermentation	Avoids costly misclassification and recalls, but event-driven, so large cost savings when incidents avoided.	Event-driven protection for SME innovators.	Minor enforcement/admin saving.	One-off adjustment cost savings.

Feed additives	22.1 million through removal of renewal obligations, streamlined modification procedures and reduced dossier and consultancy costs.	Moderate recurring saving for SME producers/formulators;	5.5 million	Recurrent administrative cost savings.
National hygiene measures	Minor recurring saving from reduced duplications.	Minor saving, esp. micro-FBOs.	Minor reduction in duplicate processing	Recurrent administrative cost savings.
Depopulation reporting	Neutral–small positive (fewer ad-hoc data calls)	Neutral–small positive.	Small admin saving (streamlined reporting)	Recurrent administrative cost savings.
Record-keeping for farmers	Small–moderate time saving per holding	Small–moderate relative gain for small farms	Small admin saving (streamlined reporting)	Recurrent administrative cost savings.
BSE realignment	92 million due with fewer steps and documentation in addition to lower frequency of checks.	Small–moderate share for SME slaughterhouses / renderers, proportional to throughput.	53.1 million	Recurrent administrative cost savings

Flexibility in official controls	150 million for clearance of partial consignments due to savings from reduced spoilage and demurrage costs, faster turnover of perishable goods, and fewer re-routing or disposal costs at border control posts.	Moderate–high positive for partial consignments due to spoilage reduction.	602.2 million for accreditation of NRL with fewer methods to accredit and less time and external cost for being widely accredited.	Recurrent adjustment cost savings.
Total annual savings	**At least 428 million in cost savings per year.** Large, recurring savings from scrapping routine renewals. Additional streamlining is not monetised, so the **true total is substantially higher than the quantified subtotal.**	**Highly positive impact**, especially in biocontrol and for smaller formulators/importers, via fewer renewal rounds, faster time-to-market, and better cash-flow from reduced border delays.	**At least 661 million per year.** Major structural efficiencies from risk-based renewals, proportionate accreditation and risk-aligned surveillance, plus smaller gains from simplified notifications and reporting. **The underlying savings are clearly higher than the quantified estimate**.	

ANNEX II: SYNOPSIS OF STAKEHOLDER CONSULTATION

1. Consultation approach

The Commission conducted a proportionate and targeted stakeholder consultation to inform the calibration of the proposed measures. Evidence was drawn from regular discussions with Member States authorities and stakeholders, recent evaluations and implementation reviews, in particular the pesticides legislation evaluation and the evaluation of the Feed Additives Regulation.[110] This was complemented by a targeted Implementation Dialogue on biocides with stakeholders representing businesses (active substance manufacturers, product formulators and downstream users) and civil society. No open public consultation was conducted because the initiative does not aim to alter the objectives of the legislation and addresses technical adjustments aimed at efficiency gains within the existing framework. Instead, evidence was gathered primarily via a Call for Evidence targeted at directly affected stakeholders, open from 16 September to 14 October 2025, and complemented by ad hoc consultations with competent authorities and stakeholder organisations.

The Commission received a total of 6,440 responses to the Call for Evidence on the Food and Feed Safety Simplification Omnibus. These submissions reflected a broad spectrum of views from citizens, businesses, NGOs, public authorities, and academic institutions. Nearly 6,000 submissions came from citizens, largely as part of organised campaigns. Among institutional stakeholders, 318 replies were submitted by business associations, 52 by public authorities, 107 by NGOs, and 16 by academic organisations. In addition, 319 detailed position papers were shared, providing in-depth feedback on specific legislative areas and simplification measures.

The sections below present stakeholder views from the Call for Evidence primarily, by topic, indicating where positions converge or differ and noting any concrete operational suggestions. Overall, input has been used to refine the problem definition, prioritise certain options, and shape safeguards.

2. Stakeholder views by topic

2.1. Plant Protection Products

Biocontrol

Making new active substances and PPP alternatives available is fundamental to fill gaps left by products no longer authorised, and to provide a larger variety of substances with different modes of action to mitigate the occurrence of resistances. Farmers want to use safe and effective products and therefore ensuring the availability of biocontrol active substances and PPPs plays an important role.

Member States have also called for the urgent need to safeguard the tools needed for farmers, including access to chemical PPPs, as evidenced in the Agriculture and Fisheries Council meetings in June and July of 2025. Member States have also repeatedly indicated, either via

[110] SWD(2020) 87 final and SWD(2024) 46 final

the Call for Evidence, in bilateral meetings, or through working groups of Chief Plant Health Officers, the need to ensure availability of plant protection products for the purposes of implementing Regulation 2016/2031.

Industry stakeholders, including farmers, highlighted the importance of facilitating access to market of biocontrol active substances and products but underlined that it would be too simplistic to consider biological active substances as "1 to 1 replacement" for banned chemical active substances. A more holistic approach would need to be taken into consideration in this transition to ensure farmers have affordable and effective tools to fight pests. Citizens often referred to the European Citizens Initiatives 'Stop Glyphosate' and 'Save Bees and Farmers' to ensure that the Omnibus Initiative does not lead to any regression in the protection of health, biodiversity, and the environment but promotes biopesticides and other low-risk plant protection products.

According to stakeholders, some plant pests affecting certain crops would need a more urgent biological solution available as the synthetic chemical active substances used to combat such pest are either no longer approved (with no current alternative), or at risk to be withdrawn from the market, or approved under too stringent conditions (e.g., low MRL making their effectiveness critical), or not offering a substantial differentiation of modes of actions. This is particularly true for (but not limited to) herbicides/weed control substances as the group of biocontrol active for this function has not been developed by applicants; this is more valid across several types of crops (cereals, cotton, fruits and vegetables, oilseeds, rice) for insecticides (cereals, fruits and vegetables, hops, olive groves, potatoes, seeds, sugar beet), and fungicides (fruits and vegetables, hops, olive groves, ornamentals, potatoes, rice, seeds, tobacco). While no crop has been entirely abandoned solely due to a lack of active ingredients, the steady withdrawal of active substances and PPPs has led many growers to gradually discontinue certain crops, posing them at abandonment risks in certain areas. Stakeholders highlighted that in view of those data, there would be an urgent need for new biocontrol solutions. However, according to stakeholders, exerting control of some diseases, e.g. against fungi and weeds, by employing solely biological substances remains unfeasible with the current available technology. Industry stakeholders recognise the value of biological PPPs when combined with conventional PPPs, especially for finishing treatments when pest pressure is low and to help reducing residues at harvest. This suggests that the need for having more rapid biocontrol PPPs available on the market must be combined with increased research and innovation to allow new technologies gaining more efficacy and trust from farmers.

Basic substances

In the Call of Evidence, many competent authorities suggested to clarify and harmonise rules on basic substances. Already during previous ad hoc consultations of Member States and via specific reactions of industry stakeholders on basic substances several aspects were identified as in need of clarifications. The previous feedback revealed that there are insufficient provisions for the labelling of products containing basic substances and inconsistencies between the conditions of approvals set at the EU-level with the market reality. Several Member States also reported problems related to the cross-border trade of basic substances-containing products and the limited use of products containing basic substances in agriculture because the formulation and packaging is not suitable for professional uses. In addition, the co-existence on the EU market of products containing the same substance as active substance and

as basic substance is perceived as generating distorted pricing for the same compound and limitations of use for certain sectors.

Furthermore, in the Call of Evidence, growers call on the European Commission to ensure that substances once approved as basic substances are available to farmers in all Member States and that the basic substance status cannot be superseded by an approval as "regular" active substance. Industry is also concerned with this issue and asks for clarification of existing rules so that market distortion and legal uncertainty is avoided.

Finally, growers also indicate a need to streamline the approval procedures for well-known low concern substances, such as basic substances.

Active substances

Growers, farmers and Member States are very concerned about the reduced number of approved active substances and the lack of viable alternatives to pest control. Some highlight the importance of ensuring a range of solutions and not relying on biocontrol only. Delays, complexity in and costs emanating from the existing regulatory system, alongside the overall difficulty in placing plant protection products on the market are a significant concern of companies affected. As highlighted in the evaluation of Regulation (EC) No 1107/2009, feedback to this Call for Evidence reiterated that delays occur across all work streams, including active substances and PPPs. The periodic renewal of all active substances and PPPs appears to be a substantial contributor, as it requires vast amounts of resources. Such delays slow down the access to market access for innovative PPPs and lead to a lack of predictability for industry and farmers. Businesses ask for transparent criteria to select substances into a full renewal procedure, for published timelines/service standards for initiating and concluding targeted reviews, and for clear escalation pathways if new risks emerge. A minority cautions against any weakening of scrutiny and seeks explicit commitments on post-authorisation vigilance and communication that protection levels are unchanged. Many respondents also point to the increasing number of active substances no longer approved while very few new alternative active substances are being approved. This might increase the risk of resistance development and has led to more requests for emergency authorisations under Article 53 of Regulation (EC) No 1107/2009. Several respondents would like to see the principle of no non-approval without the availability of an alternative enshrined in the legislation. Growers, but also industry, ask further for strengthening of the use of Article 4(7), the possibility to approve under conditions of negligible exposure, the use of precise application techniques, stronger support for minor uses and for risk-based decision making.

NGOs call on the European Commission to ensure that the simplification of food and feed safety legislation does not weaken environmental or health protection and that the high level of protection enshrined in primary EU law is maintained, as well as ensuring existing safeguards in the regulation on pesticides are not weakened. This is also echoed by water suppliers pointing towards pesticides as a major pressure on the status of water bodies in the EU. NGOs further consider that derogations should remain strictly justified, time-limited, and backed by independent scientific evidence. Specific concerns about impacts of use of pesticides on biodiversity were raised by several NGOs and citizens with some respondents calling for a strengthening of the pesticide regulation instead of a simplification and for a reduction in

pesticide use. One NGO considers there is a need to include measures to phase out animal testing.

Researchers and academics expressed mixed views, some criticising the existing system as being outdated and obstructive and hindering innovation whereas others expressed the need to ensure existing protection and safeguards are maintained.

Feedback from citizens mostly points towards concerns about use of pesticides for health and the environment and call for no weakening of regulations and even for a phase out of pesticides.

One Member State expressed concerns about ensuring up-to-date risk assessment if approvals are no longer systematically renewed and fears slower authorisation processes and de-harmonisation if Member States would have to reinterpret the available data on the basis of newer assessment guidelines without a previous EU level assessment. Overall, contributions from Member States and industry stakeholders show support for reducing unnecessary renewal-driven burden, but stress that any change to the current system, including a move away from systematic, time-based renewals, must be accompanied by clear criteria for targeted reviews and safeguards to maintain the existing high level of protection.

Authorisations

Industry stakeholders and farmers expressed concern about the lack of harmonisation of authorisation procedures in Member States. As a result, they called for harmonisation and simplification of authorisation processes, which should in turn speed up the issuance of new and renewal of existing PPP authorisations. However, as indicated by consumer associations, environmental NGOs, and public health NGOs, simplification must not come at the expense of human and environmental safety.

Comments on mutual recognition and the minor uses extensions were essentially in the same direction. All relevant stakeholders considered that the potential of a simplified pathway for these two specific types of authorisations has not been realised at Member State level, leading to delays, higher costs and lower availability of plant protection products. This, in turn, has a negative impact on the response time to threats emerging ever faster due to climate change. They also pointed to the role of independent scientific evaluation of plant protection products and the role of agroecological practices in reducing pesticide dependency.

Mutual recognition

Industry and farming stakeholders provided information on the numbers of applications submitted per year, delays of Member States in assessing requests, and estimated monetary losses of companies due to these delays. According to their association, relevant agrochemical producers submit 3.6 requests for mutual recognition to 4.6 Member States yearly. Average delays of Member States in assessing these requests are 163 and 356 days for Zonal Mutual recognition and Interzonal Mutual recognition applications, respectively.[111] In the Call for Evidence, industry stakeholders primarily expressed a view that the mutual recognition of

[111] beyond the 120 days provided for by the Regulation (EC) No 1107/2009

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. The availability of solutions for minor crops is also a concern for some farmers, who currently do not have access to the necessary PPPs to fight pests and diseases in their cultivars.

Data protection

Several small Member States have already expressed their concerns linked to the lack of availability of plant protection products in their country due to small market size and the complex data protection rules that prevents SMEs and generic companies to enter the market. During the Call of evidence, applicants who develop and market post-patent PPPs also signalled that incumbent data protection rules are too complex, and the fragmented data protection scope hinders the placing on the market of PPPs.

2.2. Aerial spraying of PPP

Stakeholder views are relatively divergent, with many responses to the Call for Evidence reflecting widespread concern about environmental and health risks, particularly pesticide drift and exposure. Certain stakeholders still call for the retention of the derogation application system while many businesses support enabling drone application under harmonised risk-management conditions, citing precision, drift reduction and operator safety.

Among most stakeholder categories, there is cautious support for drone use in precision agriculture, contingent on strict regulatory frameworks, rigorous risk assessments, and maintaining stringent controls. While innovation and updated regulations are encouraged, stakeholders emphasise the need to uphold high standards for environmental and public health protection. There is also advocacy for reduced pesticide reliance and a transition to sustainable farming practices. Effective enforcement, monitoring, and operator certification are highlighted as essential for safe drone operations. Overall, while drones offer potential benefits, stakeholders call for balanced regulatory approaches that prioritize safety over administrative ease. If pursued, stakeholders seek EU-wide rules on pilot competence, buffer zones, nozzle/droplet specifications, digital flight logs, and integration with farm records; critics seek strict area limits and sensitive-site safeguards.

2.3. Maximum Residue Levels

A significant number of respondents expressed their support for the proposed amendments and clarifications in terminology related to pesticide Maximum Residue Levels (MRLs). They emphasized the importance of implementing clear and equitable transitional measures to prevent food waste and mitigate economic losses for farmers and food business operators. As part of previous exchanges, stakeholders representing farmers, producers and trade association had for many years requested amendments to the legislative framework on MRLs to allow for transitional measures (examples include: International Hop Growers' Convention, the German Hop Industry Association, the Hop Growers of America, The Brewers of Europe and the Hop Growers Union of the Czech Republic on MRLs for bifenazate in hops,[112] the World Wine

[112] Ares(2024)645834

Trade Group on MRLs for iprodione in grapes,[113] several fruits and vegetable industry associations from Poland on MRLs for acetamiprid in currants.[114]

Regarding third countries, the feedback was rather limited but revealed significant concerns related to the divergence between EU MRLs and international standards, abrupt changes of EU MRLs leading to trade disruptions, the inclusion of environmental factors in MRL setting, and the EU's hazard-based approach. A few third countries respondents supported establishing fair transitional measures.

2.4. Biocidal Products Regulation

When discussing actions to progress on the implementation of the Biocidal Products Regulation (BPR) and reduce delays in the review programme on the review programme, Member States and stakeholders mentioned overtime the need to give more priority to completion of the review programme. In this respect, some Member States also asked to postpone the renewal process of active substances until the review programme for first approval of existing active substances is completed[115]. During the Implementation Dialogue in July 2025, most participants acknowledged the importance of the ambitious goals set by the BPR to ensure a high level of safety for humans, animals and the environment, which will only be fully achieved with the completion of the review programme of existing active substances, and the fact that that the current rules have allowed to achieve a certain degree of harmonisation.

In response to the Call for Evidence, businesses and business associations broadly welcomed efforts to bring some simplification to the regulatory process for access to market, actions to progress on the completion of the review programme of active substances and simplify renewal procedures. Beyond the measures proposed, they considered that new technical guidance should not be applied to on-going evaluations, called for simplification of the product authorisation scheme, asked for simplification for natural or food grade active substances, ensure fair cost-sharing, and avoid any perception of reduced scrutiny for high-risk uses. A few operators asked to focus on a risk-based approach and no longer include a hazard-based approach in the management of active substances and biocidal products and emphasised the need for continuity of supply for essential disinfectants and rodenticides in certain applications. Many businesses also asked to avoid restricting flexibility on certain procedures linked to the authorisation of biocidal products families or same biocidal products, asked a reduction of fees and/or specific fees for SMEs. A few public authorities supported some simplification measures, asking to only have a risk-based approach and no longer a hazard-based approach, thus asking to maintain biocidal products that are not economically interesting and have the possibility to extend existing authorisations to minor uses, and synchronise the evaluation processes of the same active substance under different regulatory frameworks to go towards a "One Substance One Assessment" approach. A public authority asked a modification of the provisions of Article 19(5) of the BPR derogations on the use by the general public of certain products.

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[113] Ares(2019)1447179
[114] Ares (2025)3271768
115 100th CA meeting of June 2023, agenda item 5.2, 100th meeting - Expert group for the implementation of the Biocidal Products Regulation - Public Health

In the other direction, NGOs and citizens expressed strong concerns about a potential deregulation of the legislation on biocides and called on the Commission to maintain high standards for the protection of human health and the environment. In particular, NGOs considered that any modification of the BPR should be guided by the results of the evaluation started in 2025, and that the BPR should not be modified by these proposals in the meantime.

On the provisions relating related to the limitation of data protection to 31 December 2025 for existing active substances in the review programme, as set out in Article 95(5) of the BPR, some industry stakeholders as well as certain Member States requested action to provide more protection to the concerned data. A few bilateral meetings took place at the request of different industry stakeholders on this topic. Directly affected operators requested an extension of data protection for all data generated in dossier since 7 June 2018, i.e. the date of entry into application of the scientific endocrine disruptor criteria. Member States requested to extend data protection for substances in the Review Programme, at least those related to ED properties, until December 31, 2031. On the other hand, Commission services have been also contacted by companies who report difficulties in obtaining letters of access to protected data or in getting agreement from established participants to join them in the support of the substance and would thus benefit from a free access to data, e.g. SME associations indicating the importance to strive for a balance between the interest of review data owners and other actors.[116] Finally, some Member States referred also to potential difficulties of changing the rules on data protection at this stage, creating legal uncertainty for the management of applications of product authorisation submitted as from 1st January 2026 containing data that would be again protected, creating potential conflicts between the interests of companies owning concerned data and those companies who hoped to benefit from this data.

In response to the Call for Evidence, most contributions on biocides from businesses and businesses associations relate to this issue on data protection. A large number of companies and associations criticised the current hard stop to data protection for substances in the review programme, arguing it is misaligned with the extended review programme and creates free-rider risks, distorts competition, and disincentives investment in data packages, notably costly ED studies. Many explicitly supported extending or resetting protection for all data generated after 2018 and not solely those data submitted to determine endocrine disrupting properties as they argued that other updated data had to be generated due to the evolution of other technical documents or requirements, but had diverse views on what should be the extension period: until the end of the review programme; a 10-year extension from 2025 (i.e. until 2035); normal application of Article 60 of Regulation (EU) No 528/2012 which provides for data protection after the approval of a substance for a period of 10 years; up to 15 years after the decision on the approval of the active substance; until the end of the review programme or 10 years after the approval of the substance, whichever is the earliest. Manufacturers warned that companies that invested early in compliance would lose protection before competitors have to share costs, undermining innovation and supply security.

On the other hand, a few industry stakeholders would prefer not to extend data protection beyond 2025, as rules have been clear since 2013. In their view, extending exclusivity and complicating data-sharing may potentially slow authorisations if access negotiations stall, thus

116 CA-Sept25-Doc.7.11 - SMEunited feedback.pptx

discourage innovation by prolonged market protection of a few companies. Steady delays in the review programme already resulted in considerably longer amortisation of costs, and a further extension of data protection would decrease competition and keep products at high level, maintaining oligopolistic-like situations. In parallel, NGOs and citizens did not appear to provide substantive comments on this data protection issue.

2.5. Definition of GMM fermentation

Several Member States have raised the need to clarify Regulation (EC) No 1829/2003 as regards the legal status of fermentation products produced using genetically modified micro-organisms (GMM) when they contain traces from the production GMM to ensure harmonised enforcement. The matter has been discussed in a dedicated working group of the Standing Committee on Plants, Animals, Food and Feed since 2021. The same issue was raised by eight public authorities from five Member States and one EFTA country in their responses to the call for evidence. These respondents considered it should be clarified that fermentation products are not subject to Regulation (EC) No 1829/2003 if the fermentation product itself contains no GMMs or no viable cells or no high concentrations of their recombinant DNA.

The biotech and fermentation industries were of the view that GMM fermentation products that do not contain viable cells should not be regulated under Regulation (EC) No 1829/2003, and that providing legal clarity on the status of such products would align the EU with practices in other jurisdictions whilst upholding EFSA oversight. They stressed the importance of a clear framework and consistent implementation to allow them to continue using safe, sustainable GMM fermentation products in a secure and reliable legal environment. They consider that additional regulatory clarity and harmonised enforcement are key factors to increase the fermentation industry's confidence in the path to market and supporting EU competitiveness in a challenging global landscape for these products.

One respondent in the call for evidence, representing organic producers, calls for a coherent and clear clarification between "produced with" and "produced by" in the Organic Regulation (EU) 2018/848. Respondents from academia considered that the presence of trace quantities of recombinant DNA is of no regulatory concern. In the call for evidence, most NGOs that responded considered that GMO legislation should cover all products, regardless of whether these are 'produced from' or 'produced with' GMOs. In their view, such products need a proper and mandatory risk assessment. These emphasize the importance of transparent labelling and traceability of such products as GM to guarantee freedom of choice to consumers. One NGO highlighted the importance of adequate purification techniques and documented evidence that fermentation products are free of viable GMMs. Citizen responses to call for evidence included both calls to ban GMOs and to clarify that products produced with GMMs are not GMOs.

2.6. Feed additives

The proposed amendments to Regulation (EC) No 1831/2003 builds on the findings of the evaluation of Regulation (EC) No 1831/2003, which included extensive consultations on the effectiveness and efficiency of EU feed additives Regulation.[117] The details on the consultation

[117] SWD(2024) 46 final

strategy, the methodology and analysis and the results of the consultation activities are provided in Annex V to the Commission Staff Working Document on the evaluation.

Stakeholders of the feed additives supply chain, including manufacturers, traders and users, both large companies and SMEs, actively engaged in the consultation process and, after the publication of the evaluation, continued to submit to the Commission further position papers and suggestions regarding possible amendments to Regulation (EC) No 1831/2003, involving other associations of the feed chain sector.

According to representatives of the EU feed chain sector, while Regulation (EC) No 1831/2003 has served as a cornerstone of feed safety in the EU, its implementation over time has revealed some inefficiencies that disproportionately impact innovation and market access, particularly for SMEs in the animal nutrition sector. To reduce regulatory costs and administrative burden as well as to improve implementation and to ensure proportionality of EU law, the Regulation should be modernised and simplified, in particular by streamlining procedures and timelines provided for therein, which would significantly benefit the competitiveness and resilience of the EU feed additives industry, without compromising safety or environmental standards.

Such modernisation of the Regulation should especially include a revision of the authorisation system in order to better protect innovative 'non-holder specific' feed additives, the removal of the renewal requirement concerning authorisations, i.e. all authorisations should be valid without a time-limit, align with other legislation such as food additives, novel food or veterinary medicinal products, and introduce the widespread use of digital labelling for 'non-essential information' concerning feed additives and premixtures, including the possibility of voluntary labelling (claims) and the development of a EU Code of Good Labelling Practice.

According to the evaluation, national competent authorities tend to have a more positive view on the implementation of the Regulation, including coherence and relevance of the objectives, in comparison with business stakeholders' views. However, several of them acknowledged the need to improve the efficiency of the authorisation system.

In response to the Call for Evidence, almost 100 contributions were specifically submitted regarding the proposed amendments to the feed additives Regulation. More than half originated from the feed business sector and their associations, who confirmed the views provided during the evaluation and were largely supportive of the proposed measures. However, they shared requests for additional measures, such as allowing the intra-EU circulation of non-authorised feed additives intended exclusively for export to third countries, to retain industrial production capacities in the EU and maintain global competitiveness of the EU feed sector.

Ten public authorities from EEA countries also provided feedback in the context of the Call for Evidence, expressing support to the objectives and scope of the envisaged measures. Some requested further measures, such as the above-mentioned status of non-authorised feed additives intended for export, a clarification of the rules on claims and in particular the sustainability effects of additives and the controllability of labelling particulars. The United Kingdom also submitted feedback to the Call for Evidence, providing notably elements in favour of a removal of the renewal obligation for feed additives, as recently implemented in the country.

In general, both businesses and public authorities request a more substantial revision of the Regulation as a follow-up to the evaluation, while maintaining the current policy objectives of a high safety level, protection of users and effective functioning of the internal market in place. However, they call for a stronger focus on incentivising product innovation and sustainability.

2.7. Hygiene

Member States mentioned that the simplification of procedures for notifying draft national measures in accordance with Regulations (EC) Nos 852/2004 and 853/2004 will be beneficial to subsidiarity and the adoption of rules adapted to local needs, where necessary. This simplification will also contribute to more transparent and efficient procedures.

2.8. Animal welfare

In April 2025, Member States were asked by the Commission to provide information on their views, challenges and experiences related to the reporting on depopulation operations required by Article 18 of Regulation (EC) No 1099/2009. Replies were received from nine Member States.

Some of these Member States described problems with the current reporting system, including a lack of common definitions and incoherent reporting of challenges faced when performing depopulation activities, which hampers the comparability and usefulness of the information provided. In addition, several Member States complained about double reporting requirements and suggested that such information should rather be included in the Member States' annual reports under the Official Controls Regulation, as is currently the practice in many Member States already.

2.9. BSE surveillance

Misalignment of the EU legislation with WOAH international standards, adopted in 2023, and the recent EFSA scientific opinion on BSE risk posed by ruminant collagen and gelatine derived from bones, published in 2024, have been flagged repeatedly by stakeholders and Member States in PAFF Committee meetings, Chief Veterinary Officers meetings, the Animal Health Advisory Committee, and the EU TSE Working Group. Consultations performed in support of the ongoing evaluation of the Animal Health Law (AHL) also indicate that excluding TSEs from its categorisation process creates confusion, hinders prioritisation, and leads to inefficient allocation of resources.

Industry, operators, farmers, NGOs, and competent authorities all welcomed alignment with WOAH standards, simplification of procedures, greater legal certainty, and reduced administrative burden while maintaining strong safeguards for animal and public health. Some academics, EU citizens, and a few manufacturers, shared concerns in regard to the complexity of existing rules and warned against diluting BSE/TSE protections, stressing the importance of maintaining strict surveillance, testing, and feed prohibitions.

Beyond the scope of this omnibus, research institutions pointed to burdensome import permit procedures under the ABP Regulation, while some stakeholders opposed the intraspecies feeding ban for fish in Regulation 999/2001, arguing it lacks scientific justification and limits

sustainable resource use. A few respondents went further, calling for repealing the current BSE Regulation and integrating its essential provisions into broader animal health or food safety legislation.

Overall, the consultation reflects broad support for a science-based, risk-proportionate update, tempered by calls to ensure that the EU framework will keep the high level of animal and public protection.

2.10. Official Controls Regulation

Partial clearance of consignments

The possibility to accept the partial clearance of consignments of plant and plant products at border control posts (BCPs) has been requested repeatedly by food business operators and their associations, who are concerned about the lack of flexibility and the spoilage of perishable goods. Similarly, Member State authorities have requested flexibility several times already during meetings of the Plant Health section of the PAFF committee, and of the Working Party of Chief Plant Health Officers.

In the Call for Evidence, directly affected operators and their associations broadly support the measure. They expect a reduction of storage costs at Union entry points and fewer delays in perishable food supply chains, without weakening the reliability of phytosanitary controls. This support is conditional on uniform implementation and clear, harmonised procedures by the competent authorities in Member States. They also expect implementing rules describing control procedures, splitting process, and the adaptation of IT platforms made available by the authorities (TRACES and national customs systems). In short, this measure is perceived as an effective measure that provides targeted efficiency while preserving the rigor of controls.

Laboratory accreditation

The exemption from laboratory accreditation, in certain conditions, has been repeatedly flagged by Member States and by EURLs, e.g. those for food contact materials and feed additives hosted by the JRC, who underlined that the current framework is not proportionate to operational realities. The issue was raised, during several meetings of the Plant Health section of the PAFF committee, in several COPHs meetings at the Council, and also in a meeting of EURL Directors in October 2022.

The Call for Evidence shows that a majority of stakeholders endorse the Commission's proposal to reduce administrative burden and provide more flexibility in relation to obligatory accreditation requirements for all laboratory methods in certain sectors. According to many directly affected stakeholders, it has proven unrealistic and excessively costly for reference laboratories to accredit all methods in certain sectors, e.g. to accredit all methods for each plant pest. Stakeholders indicate that the general requirement for accreditation should be maintained, and such flexibility should be limited in scope. Since there are already derogations for official laboratories stipulated in Commission Delegated Regulation (EU) 2021/1353, the same approach should be applied for the reference laboratories. Overall, the laboratories in question expect this modification of Regulation (EU) 2017/625 to facilitate a more effective use of capacities and resources.

ANNEX III: METHODOLOGY FOR COST SAVINGS

This annex sets out the approach used to quantify reductions in administrative burden. The Standard Cost Model (SCM) was applied where feasible and proportionate, focusing on measures supported by sufficiently reliable volume and time data. Quantitative estimates are provided for biocontrol (renewals), PPP (renewals), biocides (renewals), BSE surveillance adjustments, and selected OCR measures (plant-health laboratory accreditation and partial consignments). Where evidence did not support robust quantification, order-of-magnitude indications or qualitative impacts are reported on the basis of conservative assumptions. Unless otherwise indicated, figures are indicative and reflect steady-state annual effects; they are intended to inform the expected scale and distribution of savings rather than replace a full impact assessment.

The estimates should be read as ranges rather than precise point values. They draw on partial and heterogeneous data across Member States and sectors, and rest on simplifying assumptions on volumes, time spent and wage rates that may not fully reflect local practice or learning effects. Baselines and prices are fixed to a reference year, while inflation, fee schedules and salary scales will evolve. For renewal-related measures, forward-looking volumes of applications are uncertain, and steady-state assumptions may understate short-term transition costs or overstate near-term savings. Some effects are distributional and may shift effort between authorities and businesses, rather than provide a net reduction. To limit double counting, savings were allocated conservatively where measures interact, though a residual overlap risk remains. Where evidence gaps persisted, parameters were proxied or triangulated from evaluations and implementation reports; otherwise, impacts are described qualitatively. Overall, the figures should be interpreted as order-of-magnitude indications of scale and direction.

1. Methodology for the calculation of cost savings from the proposed amendments to Regulation (EC) No 1107/2009 (PPP Regulation)

Despite efforts to collect data on costs through specific queries addressed to relevant stakeholder groups (in addition to Eurostat data and other publicly available data), it was not possible to find cost figures for all intended measures. Therefore, cost estimates should be considered only as an approximation of the cost savings for the different stakeholders. The following costs savings were considered and were quantified as far as possible with the data available. Where quantification was not possible or only partially possible this was highlighted as uncertainties.

1.1 Calculation of cost savings due to unlimited approval periods for most active substances

Expected cost savings due to unlimited approval periods for most active substances were calculated for substances with an expiry date in the reference years 2033-2035, as applications for renewal of approval of substances expiring in those years must be submitted not later than 3 years before the expiry of approval of the active substance concerned. The listed active substances are thus the first substances expected to be impacted by the proposal. It is to be noted, that the listed substances exclude candidates for substitution as for those unlimited approval periods are not proposed and basic substances for which a renewal process is not required.

Average cost saving per year for applicants were calculated taking into accounts both dossier costs and fees required by Member States (see table 1 below).

Dossier costs

Data were provided by stakeholders on dossier costs for chemical substances (shown in regular font in table 1) and for biocontrol substances (shown in bold and italics in table 1). Knowing the number of biocontrol substances and the number of chemical substances that will expire in the time span 2033-2035, the sum dossier costs were calculated per year as weighted sum and then averaged over the time span 2033-2035. Following this method, the average dossier costs for chemical substances amounted to 8,555,585 Euro per active substance, while the average dossier costs were about 7 times lower for biocontrol substances (1,211,250 Euro per active substance).

Fees

Data on fees per Member State per year were communicated to the Commission in 2025 following a survey with Member States or were taken from publicly available sources on the internet, except for those indicated with an asterisk for which values from the evaluation were taken.

Several Member States charge an extra fee if there is more than one applicant, more than one representative use, to process comments received or if the file requires more work than originally foreseen. Per renewal file there is also a co-Rapporteur Member State for which some Member States also charge a fee. The total cost saving will, therefore, be higher than the estimate provided below.

There was no indication that fees for chemical substances and biocontrol substances would be different, therefore the same average values for fees provided by Member States were taken for all substances.

Table 1: Dossier costs and fees for active substances with expiry date in 2033-2035. Substances in bold and italics are biocontrol active substances, substances in normal font are chemical active substances

2033	2034	2035
Acetamiprid, RMS: DE Fee: 176.100 EUR	Tribenuron, RMS: FR Fee: 260.000 EUR	Metalaxyl-M, RMS: DE Fee: 176.100 EUR
Silthiofam, RMS: NL Fee: >380.000 EUR	Isoxaflutole, RMS: SE Fee: 605.500 EUR	Foramsulfuron, RMS: FR Fee: 260.000 EUR
Forchlorfenuron, RMS: ES Fee: >190.840 EUR	Carvone, RMS: IT Fee: >137.000EUR	Pyriproxyfen, RMS: ES Fee: >190.840 EUR
Zoxamide, RMS: BE Fee: >200.000EUR	1-methylcyclopropene, RMS: DE Fee: 176.100 EUR	*Pythium oligandrum* strain B301 RMS: not set yet, original RMS BE Fee: >200.000EUR
Trifloxystrobin, RMS: HR Fee: case by case negotiated with the applicant	Dimethenamid-P, RMS: BE Fee: >200.000EUR	**Lavandulyl senecioate**; RMS: SE Fee: 605.500 EUR
Carfentrazone-ethyl, RMS: FR Fee: 260.000 EUR	Tolclofos-methyl, RMS: FI Fee: >200.000EUR	**Ferric pyrophosphate**, RMS: CZ: Fee: >10,395EUR
Pethoxamid, RMS: AT Fee: >~400.000EUR	***Clonostachys rosea* strain J1446**, RMS: HU Fee: 30.612 EUR	***Phlebiopsis gigantea* strain VRA 1835**, RMS: EE Fee*: 23100 EUR
Laminarin, RMS: EL Fee: >~40.000EUR	**ABE-IT 56, RMS: FR** Fee: 46.000 EUR	***Phlebiopsis gigantea* strain VRA 1984**, RMS: EE Fee*: 23100 EUR

2033	2034	2035
***Pasteuria nishizawae* Pn1**, RMS: NL Fee: >170.000 EUR	***Bacillus subtilis* strain IAB/BS03**, RMS: ES Fee: 40.456 EUR	***Phlebiopsis gigantea* strain FOC PG 410.3**, RMS: EE Fee*: 23100 EUR
***Ampelomyces quisqualis* strain AQ10** RMS: SE Fee: >275.230 EUR	***Verticillium albo-atrum* strain WCS850**, RMS: NL Fee: >170.000 EUR	**Sodium hydrogen carbonate**, RMS: AT Fee: 130000 EUR
Glyphosate, RMS: not appointed yet, previously the Assessment Group on Glyphosate ('AGG': FR, HU, NL and SE) Fee > 605.500 EUR 118		
Total 2033 fees (excluding trifloxystrobin): 2.697.670EUR **Average 2033 fee per active substance: 245.242EUR**	**Total 2034 fees: 1.865.668EUR** **Average 2034 fee per active substance: 186.567EUR**	**Total 2035 fees:1.642.135EUR** **Average 2035 fee per active substance:164.214 EUR**
Estimated average dossier cost (without fees) chemical active substance (X): 8 517 537 EUR 119	**Estimated average dossier cost (without fees) chemical active**	**Estimated average dossier cost (without fees) chemical active**

118 The fee requested by the AGG is not known. This figure is estimated based on the fee requested by SE and is expected to be higher given the volume of the file and the necessary coordination.

119 Data provided by stakeholders on average costs for renewal dossiers of chemical active substances (8 750 000 €) where only available with MS fees included. To have the average dossier cost without fees, the average fee was then deducted (i.e., 8 750 000 € - 232 463 € = 8 517 537 €),

2033	2034	2035
Estimated average dossier cost (without fees) biocontrol active substances (Y): 1 211 250 EUR 120 **Estimated total dossier cost (without fees) as weighted sum: 8X+3Y= (8* 8.517.537 EUR) + (3* 1.211.250 EUR) = 71.774.046 EUR**	**substance (X): 8 563 433 EUR 121** **Estimated average dossier cost (without fees) biocontrol active substances (Y): 1 211 250EUR 122** **Estimated total dossier cost (without fees) as weighted sum: 6X+4Y= (6* 8.563.433 EUR) + (4*1.211.250 EUR) = 56.225.598 EUR**	**substance (X): 8 585 786 EUR 123** **Estimated average dossier cost (without fees) biocontrol active substances (Y): 1 211 250EUR 124** **Estimated total dossier cost (without fees) as weighted sum: 3X+7Y= (3* 8.585.786 EUR) + (7*1.211.250 EUR) = 34.236.108EUR**
Estimated total 2033 dossier costs with fees: 2.697.670 EUR + 71.774.046 EUR = 74.471.716 EUR	**Estimated total 2034 dossier costs with fees: 1.865.668 EUR + 56.225.598 EUR = 58.091.266EUR**	**Estimated total 2035 dossier costs with fees: 1.642.135 EUR + 34.236.108 EUR = 35.878.243EUR**

Table 2: Biocontrol active substances: dossier costs and fees

	2033	2034	2035
Number of biocontrol active substances expected to be submitted for renewal of approval	3	4	7

120 This is the absolute mean calculated with the "average min" (982 500 €) and the "average max" (1 440 000 €) provided by stakeholders.

121 Data provided by stakeholders on average costs for renewal dossiers of chemical active substances (8 750 000 €) where only available with MS fees included. To have the average dossier cost without fees, the average fee was then deducted (i.e., 8 750 000 € - 186 567 € = 8 563 433 €),

122 This is the absolute mean calculated with the "average min" (982 500 €) and the "average max" (1 440 000 €) provided by stakeholders.

123 Data provided by stakeholders on average costs for renewal dossiers of chemical active substances (8 750 000 €) where only available with MS fees included. To have the average dossier cost without fees, the average fee was then deducted (i.e., 8 750 000 € - 164 214 € = 8 585 786 €).

124 This is the absolute mean calculated with the "average min" (982 500 €) and the "average max" (1 440 000 €) provided by stakeholders.

	2033	2034	2035
Average fee per biocontrol active substance	EUR 245.242	EUR 186.567	EUR 164.214
Estimated average dossiers cost (without fees) on renewal of those active substances	EUR 1.211.250	EUR 1.211.250	EUR 1.211.250
Cost savings for renewal dossiers (per year)	EUR 4.369.476	EUR 5.591.268	EUR 9.628.248
n.b., calculated as: *(average fee + average dossier cost) * dossier number*	**EUR 6,529,664 on average per year** **(EUR 19,588,992 for the years 2033-2035)**		

Conclusions for biocontrol substances and other active substances

Conclusion on dossier costs:

In total the cost savings resulting from unlimited approvals on dossier costs for all the substances with an expected expiry in 3033-3035 amounted to **54,078,584 Euro on average per year.**

Conclusion on fees:

Using this methodology average fees for active substances were calculated as **198,674 Euro per year.**

Conclusion on the sum of dossier costs and fees:

Estimated cost savings as sum of dossier costs and fees would therefore amount to **56,147,075 Euro per year.**

Total costs for biocontrol active substances:

amounted to an average of EUR 6,529,664 per year (about 11,5% of the total amount of 54,078,584 Euro (Table 3), while for other active substances (excl. candidates for substitution) the costs amounted to EUR 49,617,411 on average per year (about 85,5% of the total) (Table 4).

Table 3: Other active substances than biocontrol active substances (excluding candidates for substitution)

	2033	2034	2035
Number of active substances (excluding biocontrol and CfS) expected to be submitted for renewal of approval	8	6	3
Average fee per active substance	EUR 245,242	EUR 186,567	EUR 164,214
Estimated average dossiers cost (without fees) on renewal of those active substances	EUR 8,517,537	EUR 8,563,433	EUR 8,585,786
Cost savings for renewal dossiers (per year)	EUR 70,102,232	EUR 52,500,000	EUR 26,250,000
n.b., calculated as: *(average fee + average dossier cost) * dossier number*	**EUR 49,617,411 on average per year** **(EUR 148,852,232 for the years 2033-2035)**		

1.2 Cost savings from other proposed provisions for simplification

1.2.1 Provisional authorisations for biocontrol PPP

As regards renewals of authorisation of biocontrol PPP, according to the information provided by stakeholders, the average delays are 483.5 days beyond the legal deadlines (i.e., the legal deadlines are 120 days for low-risk PPP – including biocontrol PPP – and 1 year for non-low-risk PPP) with an estimation by stakeholders of average losses in terms of missing sales ranging between EUR 1 million and EUR 3.7 million per year of delay. Expressed on a per day basis this could result in average losses per day of delay between EUR 2,740 and EUR 10,136.

With the possible introduction of provisional authorisations, a biocontrol PPP could be on the market at "day zero" after a DAR (i.e., Draft Assessment Report) would be issued by a RMS, hence on average 848.5 days before what currently happens (i.e., 483.5 days of delay beyond the legal obligations plus the current legal deadline of 365 days).

The potential cost savings due to the possible introduction of provisional authorisations, in terms of avoided losses, would then be between EUR 2.32 and EUR 8.6 million for each biocontrol PPP (ranging from EUR 2,74 per day x 848.5 days and EUR 10.136 per day x 848.5 days).

In the years 2016 – 2025 the European Commission approved 32 new biocontrol active substances, hence 3.2 / year. Assuming that, combined with the measures incentivising biocontrol PPP development, around four new biocontrol PPPs will reach authorisation per year, these per-product savings imply avoided delayed-marketing losses of EUR 22 million per year, with actual savings likely to be even higher as the number of biocontrol dossiers increases over time.

Further estimations for future cost savings for biocontrol products due to provisional authorisations are not possible as the number of dossiers that will be submitted can currently be predicted.

1.2.2. Cost savings from the amended provisions on data protection

The cost savings from the simplification of the data protection provisions are calculated based on the data provided by the industry (ECCA which is representing the post-patent companies which do not develop new active substances but only products based on already approved active substances).

According to data provided by ECCA, the average dossier cost for an application for authorisation of an innovative PPP under Article 33 where the active substance data protection expired is EUR 1,500,000 while the cost of a dossier where data matching is needed (duplication of active substance studies) as the active substance data protection has not expired is respectively EUR 5,500,000 for innovative product containing one active substance and EUR 8,800,000 for a product containing 2 active substances.

For generic products (same or similar to already authorised plant protection product e.g. the reference product) where the data protection of the active substance expired, the average dossier cost is **EUR 80,000** for Article 34 dossier (34 dossier depends solely on the data and the evaluation of the reference PPP, there are no new studies to be generated, the label is similar to the one of the reference product) and **EUR 1,050,000** for Article 33 dossier (the dossier includes also unprotected data from the reference product, newly generated data for the generic PPP, and a complete risk assessment evaluation; .thee label for the approved generic is also different from that of the reference product, incorporating new crops or varying application conditions).

If the active substance data protection has not expired, the average cost of a dossier is increased due to the data matching and amounts to EUR 5,150,000 for Article 33 dossier (new product) and EUR 4,500,000 for Article 43 dossier (renewal of already existing product).125

125 The cost is significantly higher than the average cost of a renewal PPP dossier as indicated in Table 2 as in this case they include also the fee for data matching of the active substance data for which the data protection has not expired.

Therefore, the average costs vary significantly depending on the data protection status of the active substance data:

- For innovative PPP –increase from EUR 1.45 M to EUR 5.15 or EUR 8.85 M (depending on one or two active substance data matching dossiers being generated for a PPP)

- For article 33/34 dossier or article 43 –increase from EUR 1,050,000 to EUR 4.75 M (assuming one data matching dossier)

- Article 34 dossier or renewal dossier of a generic product–increase from EUR 80,000 to EUR 3.78 M (assuming one data matching dossier)

Based on the above, the difference between a plant protection dossier where the active substance expired (without data matching) and a plant protection dossier where the active substance data is still protected (with data matching) is on average EUR 3,700,000. This sum includes the price of a letter of access (license to use the data for which protection has not expired) or the costs to conduct duplicate studies in order to "compensate" for the active substance studies that are still protected.

ECCA estimates that the half of the data matching dossiers generated by its members are actually not necessary as the data protection of the active substance studies was artificially extended due to the fragmentated territorial scope combined with the delays in the risk assessment at Member State level. Therefore from 8 data matching dossiers per year, 4 could be spared thus generating a cost savings of **EUR 14,800,000** annually only for the ECCA member companies (EUR 3,700,000 being the difference between a dossier with data matching and dossier without data matching multiplied by 4).

1.3 Impact on SMEs

If high dossiers costs and delays of assessments are concrete issues which biocontrol manufacturers in the EU struggle to face, this is particularly true for SMEs, which are typically characterised by a lower turnover compared to bigger companies.

To provide a practical example on how these costs have a dramatic impact on SMEs, a micro-sized enterprise manufacturing biocontrol claimed in a recent meeting with DG SANTE that only the cost of the renewal dossier of one of its active substances amounted up to 1.5 years of its turnover. This underlined the high investments these companies must commit to, without any guarantee of a quick profit.

These difficulties are widespread across biocontrol manufacturers in the EU since, according to stakeholders' representatives:

the 90% of EU biocontrol manufacturers are SME,

the number of SME (i.e., <50M turnover) operating in the EU is 149, of which almost a half (i.e., 71 companies) are "micro-sized" (i.e., <2M Euro turnover).

This data highlights how the structure of the market of biocontrol is dominated by SMEs, therefore particular attention on facilitating access to market of biocontrol should be contextualised into the SMEs remit.

In this regard, for analogy with the calculation made above in the sections above “Cost savings due to possible introduction of permanent approval/authorisation of biocontrol”, the savings due to possible introduction of permanent approval of biocontrol active substances for the years 2033, 2034 and 2035 would be EUR 17,630,093 for SMEs (i.e., 90% of the sum of the cost savings for the years 2033, 2034, and 2035 calculated in Table 3, Annex 3 (EUR 19,588,992). This would mean savings of EUR 5,876,698 annually. N.b., due to unavailability of data on biocontrol PPP renewal dossiers which will be submitted, this estimation was limited to data on renewal of approval of active substances.

1.4 Overall cost savings under Regulation (EC) No 1107/2009

Measures included in the SANTE Simplification proposal*		**Estimated costs savings in EUR per year**
Biocontrol active substances - unlimited approvals		**6,529,664 (dossier costs and fees)**
Provisional authorisations for biocontrol products		22,000,000
Other active substances* - unlimited approvals		**49,617,411 (dossier costs and fees)**
Basic substances		**N/A**
	Mutual recognition	N/A
	Minor uses	N/A
	Treated seeds	N/A
Data protection		**14,800,000**
TOTAL		92,947,075

* This includes all other active substances except candidates for substitution, basic substances and biocontrol active substances.

2. Methodology for the calculation of costs saving from the proposals on the Biocidal Products Regulation (EU) No 528/2012 (the BPR)

The cost assessment is based on the situation of active substances approved under the Biocidal Products Regulation (EU) No 528/2012 (BPR) as of 1 September 2025, assuming the Omnibus proposal is adopted and applied from 2027 onwards. Given that a full evaluation of the BPR is starting in 2025, the figures presented are **illustrative**. They draw mainly on the 2009 Impact Assessment for the BPR, updated to 2025 prices, and complemented by current information on ECHA fees, Member State fees and the renewal pipeline. More precise data will be generated in the context of the BPR evaluation and used for subsequent initiatives.

The exercise is deliberately narrow in scope: it quantifies only the **cost savings for industry** from removing the obligation to submit systematic renewal applications for active substances not subject to exclusion or substitution criteria. Other elements of the omnibus proposal, such as changes to Union authorisations, data protection under Article 95(5), or procedural streamlining for authorities, are expected to bring further benefits, but these could not be robustly quantified at this stage. Accordingly, the results presented here should be seen as **partial estimates** of overall savings, focusing on avoided active substance renewal applications, which represent the most significant and measurable cost driver for the proposals presented under the BPR.

The proposal foresees unlimited approvals for active substances, except those meeting exclusion or substitution criteria. Cost savings for industry are estimated as the avoided costs of systematic active substances renewal applications. Case-by-case renewals or re-examination requested by the Commission or Member States are excluded from this estimate.

The costs have been assessed based on the situation of active substances approved on 1st September 2025 under the Biocidal Products Regulation (EU) No 528/2012 (the BPR), and assuming that the Omnibus proposal would be adopted and applied as from 2027.

Considering that a full evaluation of the BPR is starting in 2025, rough estimations are being made for the present assessment. More quantitative data will be gathered in the context of the BPR evaluation and will rather be used in that context, and for the actions that would follow as an outcome.

In the context of the current proposal, estimations are therefore made based mostly on data gathered in the Impact Assessment performed in 2009 for the proposal of the BPR revising the former Directive 98/8/EC, as well as some updated information (ECHA fees, number of currently approved substances).

2.1 On the unlimited duration of approval of active substances, except for active substances meetings the exclusion and the substitution criteria

2.1.1 Costs savings for industry

The costs savings for industry are estimated considering the number of applications for the renewal of the approval of active substances that will not have to be systematically submitted by the biocides industry if the proposal is adopted.

However, these estimations and cost savings:

- do not include the number of applications for renewal that would still have to be submitted by companies on a case-by-case for specific substances or groups of substances at the request of the Commission following discussions with Member States Competent authorities, due to the impossibility to make estimations at this stage.

- do not take into account the substances still under evaluation in the review programme set out under Article 89 of Regulation (EU) No 528/2012 that will eventually be approved in the coming years, and that would be/would have been normally subject to requirement of the systematic renewal of approval due to limited duration of approval as currently applied in the BPR.

To quantify the costs savings for industry, the following method is followed:

- the number of applications for renewal that will not have to be submitted is estimated (A)

- the average cost for application for renewal an application for renewal is estimated (B); it covers cost related to the gathering of required data in application dossiers

- the fees paid to the European Chemicals Agency is estimated (C)

- the average fee paid for an application to the evaluating Competent Authority (D)

The costs savings for industry = A* (B+C+D).

Number of applications for renewal of approval that will not have to be submitted

The following is considered for the estimations:

- an application for renewal corresponds to an application submitted to renew the approval of one active substance for one product-type (PT) as defined in Annex V to the BPR. When an active substance is approved for several PTs, an application for renewal needs to be submitted for each PT.

Table 5 provides an overview of the deadlines for the submission of applications for renewal of approval for active substances, for which the application for renewal is currently under evaluation or will have to be submitted in coming years and indicating whether the active substance is already known to meet the exclusion or substitution criteria[126].

Table 5

Year of submission	Normal substance	Exclusion	Substitution	Total
2018	3	1	1	**5**

[126] As stated in their current approval regulation, or due to the hazard classification of the active substance, in the light of the criteria set out in Article 5(1) and 10(1) of the BPR.

Year of submission	Normal substance	Exclusion	Substitution	Total
2019	1	0	0	**1**
2020	3	3	0	**6**
2021	4	1	2	**7**
2022	6	8	1	**15**
2023	16	2	1	**19**
2024	21	4	3	**28**
2025	23	0	9	**32**
2026	38	0	0	**38**
2027	27	0	0	**27**
2028	1	1	1	**3**
2029	2	1	0	**3**
2030	12	1	2	**15**
2031	5	0	0	**5**
2032	11	0	0	**11**
2033	15	0	0	**15**
2034	4	0	2	**6**
2035	5	0	0	**5**
Grand Total	**197**	**22**	**22**	**241**

If the proposal is adopted and applicable as from 1st January 2027, excluding substances meeting exclusion or substitution criteria for which a systematic renewal application would always be requested, at least **82 applications[127] for approval would no longer have to be submitted (corresponding to 35 active substances for one or more product-types) for the period 2027-2035.**

Such figure is a low estimation on the long-term costs savings, as it can be assumed the majority of the active substances currently under evaluation for their renewal of approval would obtain their renewal and would eventually still not be meeting exclusion or substitution criteria (i.e. applicants

[127] 27+1+2+12+5+11+15+4+5= 82 applications

submit all required data for the assessment, conditions for approval still met)[128] Furthermore, more substances still under assessment in the review programme set out in Article 89(1) of the BPR will eventually be (firstly) approved in the coming years and will not meet the exclusion or substitution criteria.[129]

Average cost for an application for renewal of approval

No specific study would be carried out on the matter for the preparation of the current proposal. In the Impact Assessment performed in 2009 for the proposal of the BPR revising the former Directive 98/8/EC, the cost of preparation of an application for approval of an active was estimated between EUR **3 to 5 million,** based on a study performed in 2007.[130]

On one hand, the cost of constitution of an application for (first) approval is supposed to be higher than the cost of a renewal application, considering most of the data and previous testing on the properties of the substances would still be valid. In addition, most of the data required to assess the substance for one product-type will be valid to assess other products-types for the same active substance, making the cost of constitution of subsequent applications for additional PTs for the same active substance less important.

On the other hand, some testing methods have evolved overtime, and updated data may be needed in certain area in the light of scientific progress. Additionally, companies must usually provide in their application since 2018 additional testing to assess the scientific criteria for the determination of endocrine-disrupting properties[131], as in many cases the data package available before that date would not be sufficient to assess those criteria. Testing of ED properties may involve vertebrate testing, which are usually known to be costly compared to other testing (ex: testing of physico-chemical properties).

Taking into account the above considerations, and that cost savings on the renewal data package for dossiers compared to the first approval dossier may be compensated by other costs (some updated tests, ED testing, other), and in absence of a revised study to assess the real costs in 2025 for the constitution for a renewal dossier, the same figures as in the Impact Assessment performed in 2009 for the proposal of the BPR will be used as an estimation.

The cost of preparation of an application for renewal of approval for an active substance is therefore estimated between EUR 3 to 5 million in 2007. Corrected with inflation[132], and take into account other costs for applicant, i.e. costs linked to contracting consultancies to help them build an

[128] In the best-case scenario that all current approvals are renewed, it could be up to 197 applications that would no longer have to be submitted on the long term, corresponding to 101 active substances for one or more product-types)

[129] Around 305 dossiers are still under assessment in the review programme, for 109 active substances for one or more product-types

[130] See pages 13, 14, 85 and 86 of Commission Staff Working document Accompanying document to the Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products, Impact assessment, SEC(2009)774, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009SC0773

[131] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

[132] Considering a cumulated inflation of 54% in the EU over the period 2007-2025, annual inflation as measured by the HICP (Harmonised Index of Consumer Prices) available at: https://ec.europa.eu/eurostat/databrowser/view/prc_hicp_aind__custom_17877141/default/table

application, costs of following the renewal process on the active substances for several years, and uncertainty costs linked to the outcome of the renewal procedure, the cost of preparing a renewal application in 2025 is estimated between EUR 4.6 to 7.7 million. For the sake of the present calculations, the costs are **estimated at EUR 7.7 million**.

Fees paid to the European Chemicals Agency

The fees to be paid by an applicant to ECHA to the examination of an application to renew an active substance are established by Commission Implementing Regulation (EU) No 564/2013[133].

These fees depends on the nature of the application, whether the same application submit the application for renewal of an active for one product, or whether it submit it for subsequent product-type as well (as the fee to be paid to ECHA is lower such case), whether a full or limited evaluation, and whether the applicant is entitle to benefit from SME fee reduction from 20% to 60%.

For the purpose of the present estimation:

- all companies will be assumed as not benefitting from the SME fee reduction.
- all evaluation will be considered "full evaluation", as based on experience Member States authorities consider that a full evaluation is needed in the overall majority of cases

The following fees from Commission Implementing Regulation (EU) No 564/2013 are therefore considered:

Table 6

Renewal of an approval; Article 13(3)	Fee for the first product-type for which renewal of that active substance is sought	17.925 EUR
	Additional fee for the first product-type for which renewal of that active substance is sought in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012	29.875 EUR
	Fee per additional product-type	1.793 EUR

[133] Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products Text with EEA relevance, modified by Commission Implementing Regulation (EU) 2025/1490 of 24 July 2025 amending Implementing Regulation (EU) No 564/2013 as regards the adaptation of fees to inflation.

	Additional fee per additional product-type in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012	2.988 EUR

Considering that all renewal applications are estimated to necessitate a "full evaluation" by experience, the following total fees per application are therefore considered:

Table 7

Renewal of an approval; Article 13(3)	Total fee for the first product-type for which renewal of that active substance is sought (full evaluation)	47.800EUR [134]
	Total fee per additional product-type (full evaluation)	4.781EUR [135]

Assuming that 35 active substance renewal dossiers for "first PT" and 47 dossiers the "additional PTs" (for a total of 82 dossiers) will not have to be submitted for the period 2027-2035, the total costs savings for industry from ECHA fees are estimated to: **1.897.707 EUR [136] .**

The weighted average ECHA fee savings for the period for period 2027-2035 would be **23.143 EUR** [137] for a renewal application. Compared to the costs of constitution of a renewal application estimated in section 1.2, these costs are minimal (less than 0,5% of the cost of a dossier).

Average fee paid for an application to the evaluating Competent Authority

The fees paid by applicants to the evaluating competent authorities are set by each Member States and varies a lot across the EU. Some data were gathered by the Commission services and were presented to the expert group of the Biocidal CA meeting[138], and are available online on the websites of Member States's Biocidal Competent Authorities[139]. Fees can be fixed at flat rate or can depend on the among of work spent by the evaluating authority.

Based on data collected on the fees in 20 Member States, Norway and Switzerland, the following fees can be estimated:

[134] 17.925,00 € + 29.875,00 € = 47.800,00 €
[135] 1.793,00 € + 2.988,00 € = 4.781,00 €
[136] 47.800,00 € * 35 + 4.781,00 € * 47 = 1.897.707,00 €
[137] 1.897.707,00 € / (35+47) = 23.142,77 €
[138] CA-July19-Doc.7.5 - Fees overview June 2019.docx
[139] https://echa.europa.eu/contacts-of-the-member-state-competent-authorities

- The fee for the first product-type for which renewal of that active substance is sought, for a full evaluation: it can vary from EUR 61.000 (Portugal) to EUR 625.000 (Norway), with a median **around EUR 180.000**

- The fee per additional product-type for which renewal of that active substance is sought, for a full evaluation: it can vary from EUR 33.000 (Finland) to EUR 312.000 (Norway), with a median **around EUR 75.000**

For the purpose of the present estimation, the following fees will be used:

Table 8

Fee for the first product-type for which renewal of the active substance is sought (full evaluation)	180.000 EUR
Fee per additional product-type (full evaluation)	75.000 EUR

Assuming that 35 active substance renewal dossiers for "first PT" and 47 dossiers the "additional PTs" (for a total of 82 dossiers) will not have to be submitted for the period 2027-2035, the total costs savings for industry from Member States fees are estimated to: **9.825.000 EUR** [140].

The weighted average Member States fee savings for the period for period 2027-2035 would be **119.817 EUR** [141] for a renewal application. Compared to the costs of constitution of a renewal application estimated in section 1.2, these costs represent a small portion of the renewal costs (less than 3% of the cost of a dossier).

Result calculation of cost savings for industry

Considering:

- The number of renewals not to be submitted: 82
- The costs of a dossier preparation: 7.7 million EUR
- The weighted average ECHA fee for a renewal application: 23.143 EUR
- The weighted average Member State fee for a renewal application: 119.817 EUR ,

[140] 180.000 €*35 + 75.000 €*46 = 9.825.000 €
[141] 9.825.000 € / (35+47) = 119.817 €

the costs savings are for industry coming from the unlimited approval period of active substances not meeting the exclusion or substitution criteria, which avoid the systematic submission of renewal applications, are estimated at 643.122.707 EUR for the period 2027-2035.

These savings are rounded and estimated at **643,122,707 EUR for the 9-year period 2027-2035.** This would mean **71,458,079** EUR **per year.**

In addition, evaluating Member States could re-orientate part of their resources that would have been dedicated for the renewal of approval process of these active substances to completion of the review programme and the evaluation of product authorisation applications, which would contribute to a quicker decision-making on the delayed active substances still in the review programme set up under Article 89 of the BPR and product authorisations, reducing potential costs linked to the management of those applications in the waiting of the approval/authorisations decisions. The review programme has started 2004 and the assessment of active substances has been substantially delayed, being on-going for most substances since 2004-2008.

These costs savings are difficulty to estimate and could not be quantified. However, these costs for an applicant are considered minimal compared to costs savings linked to the constitution of a dossier.

3. **Methodology for the calculation of cost savings stemming from the proposed amendments to Regulation (EC) No 1831/2003 on additives for use in animal nutrition**

This analysis estimates the costs avoided by abolishing the systematic ten-year renewal of authorisations for feed additives under Regulation (EC) No 1831/2003. It covers direct compliance and administrative costs borne by applicants (data generation, dossier preparation and internal staff time, including obligations introduced by the Transparency Regulation (EU) 2019/1381) and by public authorities (Commission/DG SANTE, EFSA, EURL-FA and Member States). Coccidiostats and histomonostats, which retain time-limited authorisations, are excluded from the saving.

Baseline parameters were taken from the Commission's 2024 evaluation (SWD(2024) 46 final) and from operational inputs provided by EFSA and the EURL-FA on the relative effort of renewals versus new authorisations. Costs reported for 2019 were first updated using the euro-area HICP accumulated between 2019 and 2024 (+19.57%). On this inflation-adjusted base, a further 14% was added to reflect Transparency Regulation obligations and, where relevant, approximately 33.5 additional staff-days per renewal dossier on the applicant side. This yields an average applicant cost of EUR 294,433 per renewal (from EUR 216,000 in 2019, inflated to EUR 258,275 and uplifted by 14%).

Average costs incurred by applicants per application for renewal of authorisation is as follows

	Estimated amount in 2019 (EUR) (before the Transparency Regulation)	**Adjusted to 2024 (EUR)** **(including estimated additional costs resulting from the Transparency Regulation)**
Average costs for applicants	216,000	294,433 (258,275 + (14% =36,158)

To provide a homogeneous overview of costs across actors in a given year, costs are presented against the expiry year of the authorisation, even though Article 14(1) of Regulation (EC) No 1831/2003 allows submission of renewal applications up to one year before expiry. The expected renewal volumes for 2025–2034 were estimated by applying the Evaluation's established method: renewals are proxied by the number of initial authorisation applications submitted 10 years earlier, irrespective of the number of additives covered per application. On this basis, and assuming that each initial application led to an authorisation granted in the year of submission, 751 renewal applications are expected over 2025–2034, with the year-by-year distribution and totals reported in the table below.

Applications for initial authorisation per year and expiry date of corresponding authorisation

YEAR OF APPLICATION FOR INITIAL AUTHORISATION	**NUMBER OF APPLICATIONS FOR AUTHORISATION UP FOR RENEWAL AT EXPIRY DATE**	**EXPIRY DATE OF THE INITIAL AUTHORISATION**
2015	41	2025
2016	57	2026
2017	55	2027

2018	82	2028
2019	83	2029
2020	96	2030
2021	112	2031
2022	82	2032
2023	83	2033
2024	60	2034
GRAND TOTAL	751	

For applicants, data requirements for a renewal are less demanding than for a new authorisation, and this is reflected in lower unit costs on the industry side. By contrast, for the Commission and Member States, the procedure for processing and adopting a renewal measure mirrors that of a new authorisation, so their processing costs are considered similar across the two cases. The EURL-FA confirmed that renewal handling typically represents about 20% of the cost of a new authorisation because new reference samples and a new evaluation report are generally not required; in these renewal cases, fees are usually not charged to applicants. For EFSA, renewal work includes internal staff time and costs for external experts (Panel and working groups). Historically, EFSA's renewal costs are around 60% of a new authorisation; since 27 March 2021, the Transparency Regulation has added specific tasks across the pre-submission (e.g. advice, public consultation on intended studies, reception/management of study notifications), submission/completeness (verification of pre-submission obligations), and risk-assessment phases (public consultation on applications, confidentiality handling). These extra tasks are estimated at EUR 16,350 per renewal on top of EFSA's renewal baseline.

All public-authority costs (Commission, EURL-FA, EFSA and Member States) were derived by multiplying the number of days spent on renewal-related tasks by the average daily rate including overheads, in line with the Evaluation. For EU administrations, the daily rate is based on the 2018 annual update of remuneration and pensions for EU officials and other servants (OJ C 451, 14 December 2018). While applicant costs are detailed above, public-authority unit costs per renewal are DG SANTE EUR 16,022; EURL-FA EUR 4,424; EFSA EUR 36,079 (comprising a EUR 19,729 renewal baseline plus EUR 16,350 for Transparency tasks); and Member States EUR 16,958 (aggregate).

Average costs incurred by the Commission, the EURL-FA and EFSA per application for renewal of authorisation, based on the number of days spent on their respective related tasks

	Estimated amount in 2019 (EUR)	**Adjusted to 2024 (EUR)**
Average costs for Commission (DG SANTE)	13,400	16,022

Average costs for the EURL-FA	3,700	4,424
Average costs for EFSA	16,500	19,729 + 16,350 = 36,079

The time to decision for renewals averages 24 months from submission to adoption. Article 14(4) automatically extends the authorisation where, for reasons beyond the applicant's control, no decision is taken before expiry; however, until the renewal regulation is adopted, outcome uncertainty remains, including on potential amendments to terms of the existing authorisation. Removing periodic renewals therefore eliminates both the recurring dossier costs and this procedural uncertainty.

Applying the above unit costs to the annual renewal counts produces the global baseline for 2025–2034. The table below shows the number of expected applications for renewal of authorisation and the corresponding costs for DG SANTE, EURL-FA, EFSA, Member States and applicants, culminating in the following decadal totals: Applicants EUR 221,119,183; DG SANTE EUR 12,032,522; EURL-FA EUR 3,322,424; EFSA EUR 27,095,329; Member States EUR 12,735,458; Grand total EUR 276,304,916. Annual averages over the decade are then used as average annual savings under the proposed measure to abolish periodic renewals. This yields around EUR 22.1 million per year for operators and just over EUR 5 million per year for public authorities.

Based on the expected number of applications for renewal of authorisation to be submitted per year for the period 2025-2034, the table below provides an estimate of the average global costs, with amounts adjusted to 2024, for the entities involved in the authorisation process:

Year	**Number of expected applications for renewal**	**DG SANTE (EUR)**	**EURL-FA (EUR)**	**EFSA (EUR)**	**MS (EUR)**	**Applicants (EUR)**
2025	41	656,902	181,384	1,479,239	695,278	12,071,753
2026	57	913,254	252,168	2,056,503	966,606	16,782,681
2027	55	881,210	243,320	1,984,345	932,690	16,193,815
2028	82	1,313,804	362,768	2,958,478	1,390,556	24,143,506
2029	83	1,329,826	367,192	2,994,557	1,407,514	24,437,939
2030	96	1,538,112	424,704	3,463,584	1,627,968	28,265,568
2031	112	1,794,464	495,488	4,040,848	1,899,296	32,976,496
2032	82	1,313,804	362,768	2,958,478	1,390,556	24,143,506

2033	83	1,329,826	367,192	2,994,557	1,407,514	24,437,939
2034	60	961,320	265,440	2,164,740	1,017,480	17,665,980
TOTAL	751	12,032,522	3,322,424	27,095,329	12,735,458	221,119,183
GRAND TOTAL	276,304,916 EUR					

For completeness, **costs for the Commission** comprise staff time across all activities required to process renewal applications. **EURL-FA costs** correspond to sample storage and maintenance and reporting limited to renewal needs, i.e. verification of applicability of previous evaluation report (≈20% of a new case). **EFSA costs** comprise internal time and external expert remuneration, with **Transparency-related tasks** accounted for as an explicit add-on per renewal. **Member-State costs** cover participation in SCoPAFF and associated implementation duties.

4. Cost savings calculations from the alignment of the EU BSE framework with WOAH Chapter 11.4.

4.1 Cost savings from BSE surveillance update

Methodology

The calculation estimates the annual savings resulting from the alignment of BSE surveillance requirements with WOAH Chapter 11.4.

Under this alignment, BSE testing would be focused exclusively on at-risk populations, leading to an estimated 85% reduction in the total number of surveillance tests performed annually.

Baseline data were sourced from the *EFSA Report on TSE Surveillance (2023)*142, The unit cost per test (EUR 12.83) corresponds to the average rate reimbursed by the European Commission under the Single Market Programme[143].

Assumptions:

- **Baseline:** 922,841 tests/year.
- **Average unit cost:** EUR 12.83/test.
- **EU co-financing rate:** 12–18%.
- **Reduction in testing volume:** 85%.

Calculations

- **Tests reduced:** 922,841 tests/year x 85% = 784.415 tests/year
- **Total direct savings**: 784.415 x EUR 12.83 = EUR 10.05 million/year
- **Distribution of savings**:
  - National authorities: EUR 8.5 million/year
  - EU budget (Single Market Programme reimbursements): EUR 1.55 million/year

Indirect operational savings from sampling, logistic, administration, and laboratory workload are not included in the above figures, but represent an additional EUR 3 million.

4.2 Cost savings from SRM list update

Methodology

The calculation estimates the annual cost savings expected from updating the list of Specified Risk Materials (SRMs) in line with the 85% alignment scenario under WOAH Chapter 11.4.

This alignment would remove the requirement to designate SRMs for healthy slaughtered bovines and would allow most fallen stock to be processed as Category 2 instead of Category 1 material under

142 The European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2023

143 WORKING DOCUMENT SANTE/2021/10502 Guidelines for the Union co-funded programmes of eradication, control and surveillance of animal diseases and zoonoses for the years 2021-2022 -20ac5c39-dc3b-453e-a424-3f8f2656eb7e_en

Regulation (EC) No 1069/2009. The calculation is based on the current volumes of Category 1 materials and average EU disposal costs weighted by disposal routes (65% incineration and 35% recovery).

Assumptions:

Source	Method of estimation	Volume (tonnes/year)
SRM from slaughtered bovines	Based on appr. 17 million bovines aged over 12 months slaughtered annually in the EU (2023 data144) and an average of 10 kg SRM per animal (skull, spinal cord, vertebral column, etc.)	170,000 tonnes
Fallen stock (on-farm deaths)	Estimated from average cattle mortality rates (2% for >24 months and 5% for <24 months) and carcass weights (350 kg and 80 kg, respectively), resulting in approximately 407,000 tonnes of fallen stock annually. Of this, around 87% is currently classified as Category 1 material under Regulation (EC) No 1069/2009.	354,090 tonnes
Total Category 1 material		524,090 tonnes/year

Under the 85% alignment scenario, approximately 445,000 t/year of Category 1 material would be reclassified in a different category, leaving around 79,000 t/year still subject to Category 1 treatment.

- **Disposal cost ranges**
  - Incineration EUR 357.5/t (65%)
  - Recovery (biodiesel) EUR 182 /t (35%)

Calculation

- Weighted average disposal cost: EUR 357.5 x 65% + EUR 182 x 35% - 232.37 + 63.7 =EUR 296.1/t
- Baseline total disposal cost: 524,090 x 296.1/t = 155.1 million/year

144 Database - Eurostat

- 85% alignment scenario: remaining Category 1 material = 78.614 t (15% of baseline)

After applying the 85% reduction, the cost for the remaining 78.614 t of Category 1 material is:

78.614 t x EUR 269 million = 23.3 million/year

This result in total annual savings of EUR 155.1 million - EUR 23.3 million = EUR 131.8 million /year

Total savings: the savings are distributed as follows:

- operators (70%) = 92.3 million/year

- authorities (30%) 39.5 million/year

5. Official Controls Regulation

5.1 Cost savings for the partial clearance of consignments of plants

This data estimates the financial impact of amending the current rules implemented in BCPs. The calculations are based on data from the year 2023.

TRACES 2023 Annual report

TRACES - Publications Office of the EU

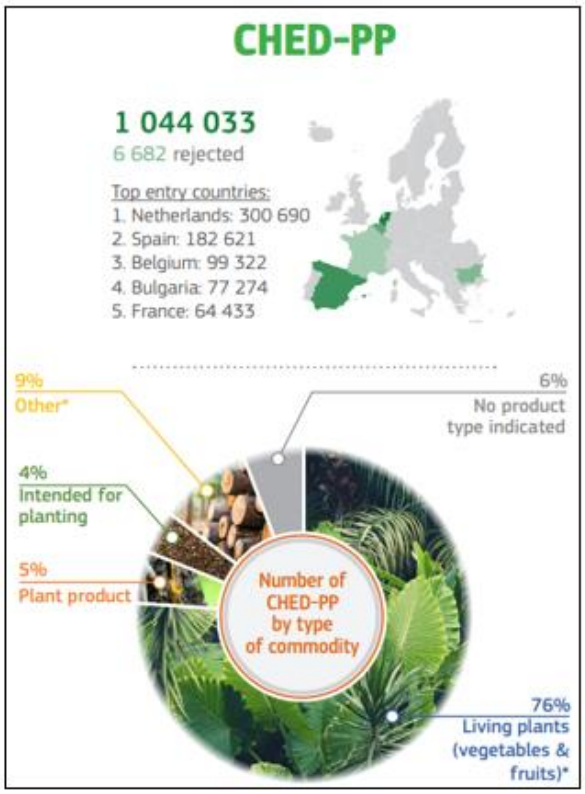


Figure 1: TRACES Annual report 2023, number of CHED-PPs created, page 11

1 044 033 CHED-PPs were created in TRACES in 2023. The Netherlands created **300 690** of these, accounting for **28.8%** of the EU total.

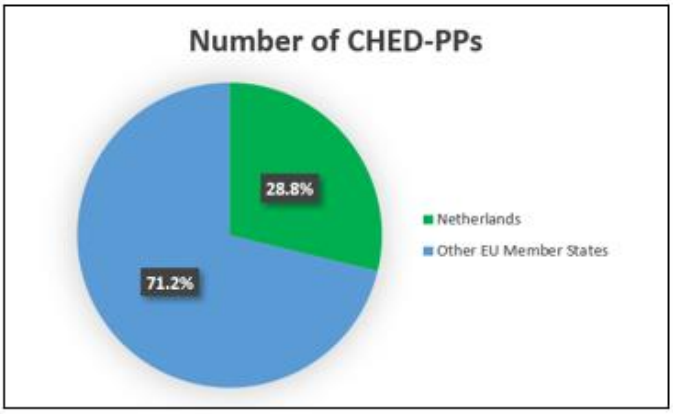


Figure 2: TRACES data 2023, Share of CHED-PPs created

Out of **1 044 033** CHED-PPs, 76% contained Living plants (vegetables and fruits). This corresponds to **793 465** CHED-PPs containing fruits and vegetables, which are perishable products with limited shelf life.

Financial impact on the operators

The financial impact of the current rules on operators can be assessed based on the figures collected from the Netherlands, which is the biggest importer in the EU.

Out of 300 690 Dutch consignments, 2965 consignments of perishable goods were subject to laboratory samples. Out of these 2965 consignments, 1198 consignments were subject to samples on only parts of consignments (On a 'lot', following Article 2(7) of Regulation (EU) 2016/2031). This means that some lots are cleared by inspectors, and others are awaiting laboratory results, meaning that a 'partial decision' was applicable in these numerous cases.

Therefore, perishable commodities being shipped within one of these 1198 consignments could be potentially lost while awaiting laboratory results.

Only 125 of these 1198 consignments were rejected for the presence of plant pests, the other 1073 were compliant and unnecessarily detained, their commodities potentially destroyed. In certain

instances, the delay in obtaining laboratory results may exceed one month, a timeframe that is more than sufficient to render perishable goods unsalvageable.

If we extrapolate this number at EU level, if 1198 consignments represent 28.8% of all consignments being partially sampled for laboratory results, we estimate the number of total EU consignments to reach 4160.

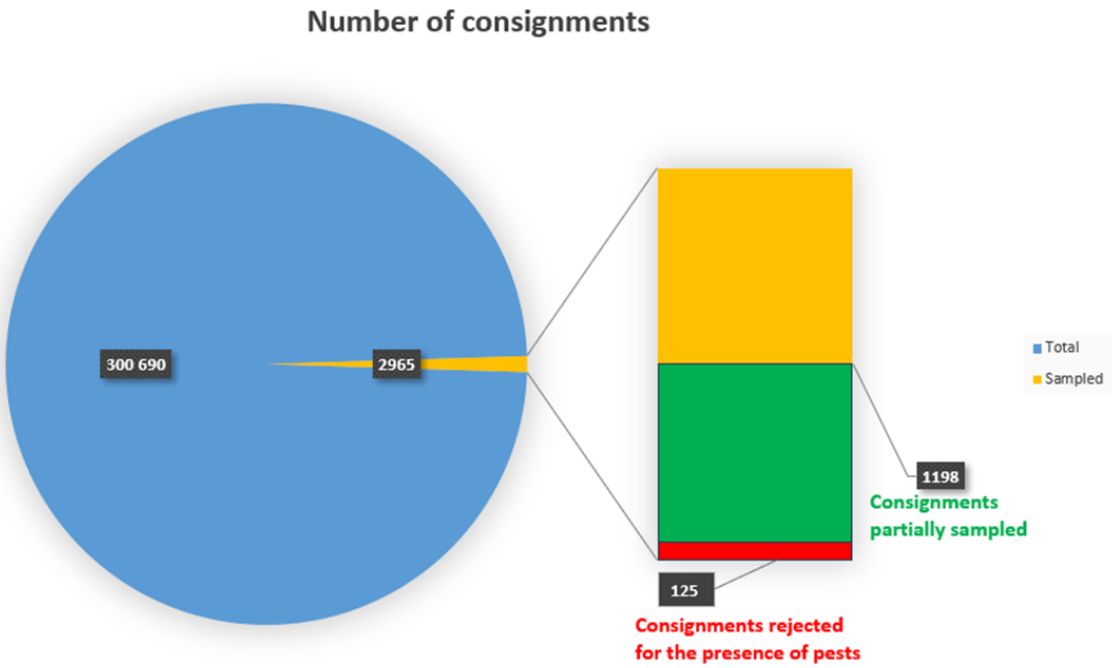


Figure 3: Number of Dutch consignments subject to laboratory samples

Estimated Economic Impact

The estimated total value of EU imports of fruits and vegetables in 2023 was almost EUR 30 million.

Chapter	**Product category**	**Value 2023 (Mio EUR)**	**Share in all Agri 2023**
07	Edible vegetables, roots, and tubers	EUR 6.622	4.2 %
08	Edible fruits & nuts	EUR 21.205	13.3 %
Total		**EUR 27.827**	**17.5%**

Figure 4: Agri-food trade statistical factsheet - Extra EU27, chapter 6,7,8 in table 'Evolution of Agri-food imports from Extra EU27, 2020 – 2023, page 8

Imports of fruits and vegetables accounted for EUR 27 827 million in 2023 and made for 17.5% of all Agri imports. It is to be noted that edible fruits and nuts are the most valuable assets in the report's

table and show the highest import share. Now, as explained above in the TRACES report, 76% of consignments were for fruits and vegetables in 2023, which accounted for 793 465 consignments, representing EUR 27 827 million.

Therefore, on average, one consignment of this type has an estimated economic value of EUR 35 070. It was estimated above that at EU level 4160 of such partially sampled consignments could carry perishable commodities that may potentially be destroyed.

This represents a potential loss of EUR 145 892 156, or EUR 146 million per year. Only the costs for fruits and vegetables were estimated. Other living plants like cut flowers could also be considered as perishable goods. This market is valued at several billion euro, and as such, the potential annual losses could exceed EUR 150 million annually.

Moreover, the data and reports referenced are based on figures from 2023. The 2024 DG AGRI report (98c0d1eb-4fb9-4b8c-87c7-8034c17b1e82_en) indicates an increase in import costs for these categories of commodities, especially edible fruits and nuts, which rose from EUR 21,037 million in 2023 to EUR 23,694 million in 2024. This category accounted for 13.8% of all agricultural imports in 2024. Based on this data, the potential loss for 2024 may exceed previous estimates.

It should also be noted that this analysis does not account for commodities contained within mixed consignments, a common occurrence in the plant health sector, which may not individually require a CHED-PP but are included as part of larger consignments and may consequently be subject to destruction during the process. These commodities are listed in Regulation (EU) 2019/2072, Annex XI, Part B.

5.2 Cost savings for accreditation of reference laboratories

COFRAC (Comité Français d'accréditation) represents the French Committee for accreditation and is the reference body in France for accreditation. This estimation is based on COFRAC Data for medium size laboratories (more than 5 laboratory experts) with one technical section, that files a dossier for accreditation for one method first within a fixed scope, then a second one later with an extension of the scope, for a period of 5 years.

To obtain and maintain accreditation, a laboratory must incur and pay various associated costs:

- Instruction fees
- Evaluation fees
- Extension fees (Optional)
- Annual fee.

4.1.1.1.Instruction fees

The application fees are intended to cover the resources used for registering the application, compiling and examining the file.

The instruction fees are divided into two components. Part A and Part B.

Part A corresponds to the flat-rate administrative fees, which cover file management and the logistical organization of the evaluation. This amount is set at EUR 442 x 2, where "2" is the coefficient applied

for one subdomain, within the fixed scope. Consequently, the cost for Part A is estimated at EUR 884 for one subdomain within the fixed scope.

Part B corresponds to the technical expertise fees, which cover the technical analysis of the file prior to the audit. The rate is set at EUR 1332 per day per assessor. The analysis is estimated to require two days, resulting in an estimated cost of EUR 2664 for Part B.

4.1.1.2. Evaluation fees

The fees associated with the assessment cover the preparation of assessments by Cofrac, the remuneration of the assessment team, logistical costs incurred, any translation costs, and the resources used to process the assessment report and notify the accreditation decision.

The assessment fees are calculated on the basis of:

- EUR 1474 per day, per person, for quality assessors and technical assessors responsible for conducting the assessment (lead).
- EUR 1352 per day, per person, for assessors and technical experts.

This results in a total of EUR 2826 per day for an audit team composed of one lead assessor and one technical assessor, in addition to logistical costs (transport, accommodation and catering) estimated at EUR 800 per team, per day.

In addition, the preparation costs represent 2% of the evaluation costs.

3 types of audits occur:

- Initial audit, estimated at 4 days.
- Surveillance audit, estimated at 2 days, every 15 months, so 4 times for 5 years.
- Renewal audit, estimated at 2 days, to renew the accreditation once every 5 years.
- Extension audit, estimated at 2 days, to extend the scope.

4.1.1.3. Extension fees

Extension fees are applicable when a laboratory applies for accreditation for an additional recognized laboratory method. For such an extension, the costs are generally similar to those of the initial accreditation but differ slightly, notably due to the shorter audit duration. For Part A of the instruction fees, the coefficient is set at 1.5 and the initial audit is estimated to last only one day.

4.1.1.4. Annual fee

The licence fees are intended to cover the various operations necessary to maintain a level of accreditation service that satisfies all the economic players concerned, from which derives the right to use the Cofrac mark.

This represents EUR 1471 per year, therefore EUR 7355 for 5 years.

TOTAL COST FOR ONE TECHNICAL UNIT WITHIN ONE LABORATORY, ONE ACCREDITATION, FOR TWO METHODS (Fixed scope + Extension)

Initial fees:

- Initial Part A instruction fees = 442 x 2 = 884 EUR

- Initial Part B instruction fees = 2 x 1332 = EUR 2664
- Initial evaluation fees = 4 days x 2826 = EUR 11304
- Initial preparation costs = 2% x 11,304 = EUR 226.08
- Initial audit logistics costs= 4 x 800 = EUR 3200

Surveillances (4 audits x 2 days, over 5 years):

- Surveillance evaluation fees = 4 x (2 x 2826) = 4 x 5652 = EUR 22608
- Surveillance preparation fees = 4 x (2% x 5652) = EUR 452.16
- Surveillance logistics costs = 4 x (2 x 800) = EUR 6400

Renewal (1 audit x 2 days, once after 5 years):

- Renewal evaluation fees = EUR 5652
- Renewal preparation fees = EUR 113.04
- Renewal logistics costs = (2 x 800) = EUR 1600

Extensions (1 audit x 1 day):

- Extension Part A instruction fees = EUR 663 (442 x (1.5)
- Extension Part B instruction fees = EUR 1332
- Extension evaluation fees = EUR 2826
- Extension preparation costs = EUR 56.52
- Extension logistics costs = EUR 800

Annual fees: 5 x 1471 = EUR 7355

Total = EUR 68135.80 for ONE TECHNICAL UNIT.

Note: A flexible scope is also available, as defined by COFRAC, and is categorized as FLEX1, FLEX2, and FLEX3. The average cost of accreditation under these flexible scopes is EUR 64043.41, which is close the fixed scope's estimated cost.

TOTAL COST FOR ALL LABORATORIES, for TWO METHODS for ONE PEST (Fixed scope + Extension)

In the European Union, National Reference Laboratories (NRLs) and European Union Reference Laboratories (EURLs) are responsible for identifying plant pests using accredited laboratory methods. These laboratories are distributed across Member States, with some comprising multiple technical sections. Each section must be accredited for the tests it performs on plant pests, using specific recognized laboratory methods.

The total number of technical units across the EU is 142.

Commission Implementing Regulation (EU) 2019/2072 Annex II lists the Union quarantine pests into 180 entries, categorized as bacteria, fungi and oomycetes, insects and mites, nematodes, parasitic plants, and viruses, viroids and phytoplasmas. Each entry may consist of a pest species, a group of species, a family or a genus. Each group, family or genus of pests may encompass multiple individual pests, in some cases several dozens. Consequently, it is estimated that this Regulation covers more than 500 Union quarantine pests. Laboratories may be assigned the task of identifying any of these listed pests.

Since a technical unit is typically specialized in a specific category of plant pests (bacteria, nematodes, etc) it only needs to be accredited for the tests performed on the pests within that particular category of specialization.

An agreement was reached at COPHs level to adopt a stepwise approach to laboratory accreditation, beginning with priority areas. These priorities include the 20 priority pests listed in Regulation (EU) 2019/1702, potato pests, pests associated with outbreaks, and pests linked to imports and imported commodities. It may be estimated that, in accordance with these guidelines, the conservative minimum number of pests requiring priority accreditation is at least 50 on average per technical section of laboratories.

Therefore, on the conservative assumption that accreditation is required for a minimum of 50 plant pests per technical section, as an average number per technical section, then the total cost is:

- 50 x 68135.80 = EUR 3 406 790 for one technical unit.
- 50 x 68135.80 x 142 = EUR 483 764 180 total cost for all reference laboratories.

Note: These estimates are based for only two methods. In practice, technical units often require accreditation for multiple methods, with the total number of recognized methods used by reference laboratories, as listed by EPPO, exceeding 20. Furthermore, plant pest detection can be performed on various matrices (plant leaves, fruits, roots, soil, etc). Detection on a specific matrix may necessitate a separate accreditation file, and another method could also require an additional file, thereby further multiplying the costs.

These factors significantly increase the costs of accreditation for laboratories. For three matrices, (fixed or flexible scope) the total costs for reference laboratories across the EU would approach EUR 1.5 billion, even assuming only two accredited methods per technical unit and for only 50 pests, which are very low numbers as compared to the total number of EU regulated quarantine pests. It is therefore reasonable to assume that the total cost of accreditation would be increased by orders of magnitude when additional pests, and multiple methods and matrices are considered.

The amendment avoids the need for technical units to be accredited for all regulated pests to be tested, but only for one main group of pests (Bacteria, viruses, nematodes, etc), meaning that if a technical unit is accredited for one method for one bacterium, the amendment grants accreditation with the same method for all bacteria.

EUR 68 000 is the cost for one technical unit over 5 years to be accredited for one pest, for two methods.

There is one pest per group for which accreditation is needed for the two methods. We consider the estimation for 3 matrices. And the final number is multiplied by 142 as the estimation is drawn for the 142 technical units.

- 68 000 x 3 x 142 = 28 968 000 over 5 years at EU level, for accreditation with 2 methods.

Annually, these equals to EUR 5 793 600 annually. Compared to the estimation of the current regime of EUR 483 764 180 annually, this is a difference of EUR 477 970 580, or a difference of 98%.

TOTAL COST FOR ONE LABORATORY, ONE ACCREDITATION, FOR TWO METHODS (Fixed scope + Extension)

In the European Union, National Reference Laboratories (NRLs) and European Union Reference Laboratories (EURLs) are responsible for detecting and quantifying feed additives and food contact materials using accredited laboratory methods. In the EU there are 2 EURLs and 54 NRLs that must be accredited for the tests they perform on FA and FCM, using specific recognized analytical methods.

For an accreditation issued by the Belgian Accreditation Body (BELAC) with one method under fixed scope and one extension:

RENEWAL assessment:

General assessment: 1 day assessment = 3500 EUR

Technical assessment one method – fixed scope: ½ day assessment = 1500 EUR

Extension assessment for one method: 1 day assessment = 3500 EUR

TOTAL = 8500 EUR

3 SURVEILLANCE assessments:

General assessment: 1 day assessment = 3500 EUR

Technical assessment of two methods under accreditation: 1 day assessment: 3500 EUR

TOTAL = 7000 EUR x 3 = 21.000 EUR

Dossier costs: 1200 EURO (one accreditation standard) x 5 = 6000 EUR

TOTAL: 35.500 EUR for 2 methods under accreditation for 5 years

AVERAGE: 3550 EUR / method / year

5.3 CONCLUSION

Given the clearly unattainable legal objectives for National Reference Laboratories and European Union Reference Laboratories to be accredited for all tests and methods for all pests, feed additives and food contact materials across different matrices due to the unreasonable associated costs, the resulting total cost at EU level is disproportionate.

In this context, a legal amendment to Regulation (EU) 2017/625 of the European Parliament and of the Council is necessary to ensure that reference laboratories in plant health, feed additives and food contact materials can operate effectively and in full compliance with EU law.

Therefore, a derogation to the requirement of mandatory accreditation for all methods used by national and European Union Reference Laboratories is needed and indispensable.

Notes:

- At present, some laboratories have already started accreditation for certain pests, while others have not yet begun. Consequently, there is currently heterogeneity in the progress of accreditation among laboratories across Member States.
- Regular mandatory proficiency tests are mandatory to maintain accreditation, while reference material and methods are lacking for numerous pests.
- In addition to cost, time represents another critical factor. Indeed, the accreditation process is lengthy and resource-intensive, encompassing compliance preparation, audit planning, and the conduct of the numerous audits themselves.
- Finally, human resources constitute a critical factor for laboratories. The time, which laboratory experts devote to preparing for accreditation, represents an increased allocation of staff to quality-related activities, to the detriment of laboratory work.