EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2025/1821
[…](2025) XXX draft

Simplification Omnibus Package

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, (EC) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

The proposal is part of the cross-cutting legislative simplification package announced in the European Commission's Vision for Agriculture and Food[1]. The aim of the package is to reduce unnecessary regulatory burdens while maintaining high standards for food and feed safety, and for the protection of human and animal health, and the environment. The proposal responds to repeated requests from stakeholders and EU Member States for faster and clearer regulatory procedures.

This initiative aims at simplifying and streamlining certain requirements and procedures for products used in the production of food and feed identified as particularly burdensome by industry and authorities. These provisions would benefit from regulatory streamlining and modernisation, which would make the respective legislation more efficient and cost-effective for industry and Member States authorities, while at the same time ensuring a high level of protection of human and animal health and the environment. More specifically, this initiative is aiming at simplification of certain provisions and procedures and ensure a better implementation of the following acts:

Regulation (EC) 1107/2009[2]: The number of chemical active substances approved for use in plant protection products in the EU is decreasing as a result of the periodic review of approvals of active substances against very strict criteria to ensure a high level of protection of human health and the environment under Regulation (EC) No 1107/2009, leaving very few solutions for farmers to protect crops against pests. Climate change also leads to the emergence of new pests and/or higher pest pressure. In line with the announcement in the Vision for Agriculture and Food[3], it is necessary to accelerate access to the market for new biocontrol active substances and products containing them in order to increase their availability to European farmers with the objective to support the shift towards more sustainable plant protection practices and reduce the use of more hazardous chemical plant protection products.

Biocontrol active substances (such as micro-organisms, semiochemicals (pheromones), plant extracts) are more sustainable alternatives to chemical active substances. However, the range of pests that those already approved today can control and the number of crops on which they are allowed to be used is relatively limited. Prospective applicants for the approval of new biocontrol active substances and/or for product authorisations on a wider range of crops complain that the capacity and expertise in Member States to conduct the necessary risk assessments is insufficient and that the time-to-market is too long. The Commission has already

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[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations, COM/2025/75, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0075

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, pp. 1–50, http://data.europa.eu/eli/reg/2009/1107/oj)

[3] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations, COM/2025/75, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0075

taken steps to facilitate placing on the market of biocontrol active substances. For instance, updated data requirements[4],[5] and uniform principles[6] for micro-organisms were adopted in 2022 to make them more fit-for-purpose, and a Single Market Enforcement Taskforce (SMET) project[7] was developed to address delays in the authorisation of biocontrol products by Member States, through sharing of good practices and solutions for more efficiency and less burden. However, the measures taken are not yet sufficient. Therefore, this legislative proposal contains several targeted amendments to Regulation (EC) No 1107/2009 to accelerate market access for biocontrol active substances and products containing them.

Several Member States, in particular smaller ones, have also signalled that applicants for the authorisation of products containing biocontrol active substances and/or low-risk active substances do not submit applications in their territories considering the limited market potential versus costs and delays related to the need to obtain authorisations in the different zones to which Member States are assigned in accordance with Annex I to Regulation (EC) No 1107/2009 and due to difficulties and delays in mutual recognition procedures. Therefore, it is proposed to reinforce the mutual recognition procedure for plant protection products containing only biocontrol or other low-risk active substances.

Article 67(1) of Regulation (EC) No 1107/2009 requires that professional users of plant protection products keep, for at least three years, records of the plant protection products they use, containing the name of the product, the time and the dose of application, the area and the crop where the plant protection product was used in order to raise the protection of human and animal health and the environment by ensuring the traceability and potential exposure, to increase the efficiency of monitoring and control and to reduce the costs of monitoring water quality. Considering that such information is less relevant for plant protection products containing biocontrol active substances, and in order to reduce the administrative burden for farmers, the obligation to keep records should not apply to plant protection products containing only biocontrol active substances.

Furthermore, experience with the implementation of Regulation (EC) No 1107/2009 and the findings of the Report on the REFIT revaluation of the pesticides legislation[8] as well as suggestions by Member States and stakeholders have shown that amending certain other provisions in the Regulation can increase clarity, address concerns about continued ability of farmers to produce crops to ensure food security, and significantly reduce administrative burdens for authorities and stakeholders without lowering the level of protection of human or animal health or the environment.

The REFIT evaluation of Regulation (EC) No 1107/2009 showed that the most significant burdens for companies and Member States relate to the procedures for approval and renewal of approval of active substances and for authorisation and renewal of authorisation for plant protection products. In particular, due to lack of resources in the Member States competent authorities, in most cases, regulatory deadlines for completing administrative procedures cannot be respected [9], causing negative impacts for farmers and industry. The workshop *Zonal*

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4 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013R0283-20221121

5 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013R0284-20221121

6 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0546-20221121

7 https://ec.europa.eu/internal_market/smet/projects/biosolutions/index_en.htm

8 https://food.ec.europa.eu/plants/pesticides/refit_en

9 Report on the compliance with the legal deadlines set out in the Regulation (EC) No 1107/2009 concerning the authorisation of plant protection products reported by Member States and Norway for the years 2017, 2018, 2019 and 2020, https://food.ec.europa.eu/system/files/2022-09/pesticides_ppp_report_ms-survey_regulatory-procedures-timing_2017-20_0.pdf

Authorisation Procedure – Improvements and Developments (ZAPID) held in 2023[10] intended to address these delays by considering different options for increasing efficiency in the assessment of applications for product authorisations. One of the findings of the workshop was that Member States dedicate significant resources to the systematic renewal of approvals of active substances followed by the renewals of authorisations of plant protection products, as these are time-limited and would expire if no applications for renewal were submitted and assessed. As a consequence, applications for approval of new active substances and first-time authorisation of plant protection products containing new active substances are often even more delayed and/or potential applicants find no Member State who is able to take on the role as rapporteur or reference Member State.

This prevents a transition towards more sustainable active substances and plant protection products. Therefore, resources in the Member States dedicated to renewal procedures should be made available for the assessment of applications for new active substances and products. Considering that most approved active substances have gone through at least one renewal process and that new active substances are expected to have better toxicological and ecotoxicological properties, it is proposed that approvals of active substances and authorisations of products containing them become unlimited in duration, except for active substances that are candidates for substitution and those approved under Article 4(7) of Regulation (EC) No 1107/2009 as these have properties that are of concern with regards to human or animal health or the environment. Nevertheless, in order to maintain a high level of protection of human and animal health and the environment, it will still be possible to set time limits for approvals if found appropriate in light of the outcome of the risk assessment prior to a decision on an approval and the Commission and Member States can periodically select a number of active substances commensurate with available resources for which a full renewal procedure would be triggered, while also maintaining the possibility for ad-hoc reviews already foreseen in Article 21 of Regulation (EC) No 1107/2009. Such an approach will lead to a more efficient use of resources as Member States and the European Food Safety Authority ('the Authority') would be able to dedicate available resources to those active substances and plant protection products for which there is a justification for re-evaluation and to the assessment of applications for the approval of new active substances and for the authorisation of plant protection products containing these substances.

Article 22 of Regulation (EC) No 1107/2009 sets out criteria to identify low-risk active substances, referring to hazard-based criteria for the substance set out in point 5 of Annex II and risk-based criteria for the plant protection products containing them set out in Article 47. Implementation of these provisions has proven difficult in practice as at the time of the approval or renewal of approval of active substances it is generally not known whether the criteria related to products in Article 47 can be fulfilled or not. The criteria are therefore simplified to only refer to the intrinsic properties of the active substance. Furthermore, there have been cases where an active substance could not be approved as low-risk because certain elements related to the criteria could not be fully clarified during the approval or renewal of approval procedure, while further information showing that these are fulfilled was generated later. However, there is currently no possibility in Regulation (EC) No 1107/2009 to apply for a change of the status of an approved active substance to low-risk. Such a possibility is, therefore, introduced.

Article 4(7) of Regulation (EC) No 1107/2009 provides for a derogation to allow for the approval of active substances not meeting the approval criteria in Article 4 and Annex II where it is necessary to do so because of a serious danger to plant health which cannot be contained by other available means including chemical and non-chemical methods with comparable costs

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

and efficacy, except for active substances having particularly hazardous properties. In such cases, all measures to reduce exposure to the active substance must be taken and consumer safety must be safeguarded. Member States authorising plant protection products containing such active substances must draw up a phasing-out plan and transmit it to the Commission. However, experience has shown that the drafting of this provision is not clear as regards its scope and should be improved to clarify for which substances such a derogation is possible. Furthermore, the obligation on Member States authorising plant protection products containing such active substances to draw up a phasing-out plan is disproportionate when considering that approvals under this provision are in any case limited to five years. This obligation is, therefore, removed and the scope of Article 4(7) is further clarified.

Following the non-renewal of the approval of an active substance, Member States must withdraw all authorisations of products containing the active substance and farmers must stop using these products. In such situations, Member States need time to enact withdrawals of product authorisations and in order to avoid creation of waste and give time to farmers to find alternatives, Article 20 (2) foresees the possibility in certain cases to provide for grace periods not exceeding maximum deadlines for placing on the market and use of existing stocks of plant protection products for which authorisations must be withdrawn. Currently Article 20(2) does not cover situations where there are no immediate concerns for human health or animal health or the environment and the reasons for the renewal are related to protection of health or the environment. However also in these situations it would be preferable that the Regulation not renewing the approval of an active substance provides for maximum grace periods that the Member States may set under Article 46 in order to enable farmers to find alternatives.

Additionally, the maximum length of graces periods specified in the current Article 20(2), i.e. 6 months for sale and distribution and 1 year for disposal, storage and use of existing stocks, might not be sufficient for farmers to get access to suitable alternatives. Increasing the maximum overall length of grace periods to 3 years would allow for an alternative plant protection product to be authorised, if necessary, thus preventing losses of revenue for farmers and ensuring food security for consumers.

A survey[11] conducted by the Authority has shown that the competent authorities of many Member States lack technical or scientific expertise to complete their tasks as rapporteur Member States withing the periods foreseen in Regulation (EC) No 1107/2009. This causes significant delays in delivering and updating draft assessment reports for applications for approval or renewal of approval of active substances, safeners or synergists. Therefore, the proposal provides for the possibility for rapporteur Member States to ask the Authority for support during the preparation of a draft assessment report for an application for approval or renewal of approval, the assessment of additional information required during the peer review process and when updating the draft assessment report after its initial submission.

The requirement for Member States to consider ‘current scientific and technical knowledge’ in the context of product authorisations has led to some confusion and divergent interpretation of what constitutes such current knowledge – in particular, if applications for product authorisations (or mutual recognition thereof) are submitted several years after an approval or renewal of approval of an active substance. This has led to divergent risk assessment outcomes among Member States and unequal access to plant protection products for farmers depending on the Member State of their establishment. Article 36(3) is, therefore, clarified to allow for harmonised assessment of the latest scientific and technical knowledge.

It has been observed that applicants have obtained product authorisations in a reference Member State having set lower fees than others in order to afterwards apply for mutual recognition of

[11] 33rd Pesticide Steering Network meeting | EFSA

these authorisations in other Member States, without, however, placing the plant protection products concerned on the market in the reference Member State having granted the first authorisation. As a consequence, farmers in that Member States have no access to the plant protection products concerned despite the existing authorisation. In order to prevent abuse of the mutual recognition system and circumvention of higher fees, application for mutual recognition of a product authorisation shall only be possible, if the product for which authorisation by mutual recognition is sought is actually placed on the market in the reference Member State. Furthermore, where companies decide to only apply in certain Member States for authorisation of a plant protection product but not in others, Article 40 is amended so that it is easier for official or scientific bodies involved in agricultural activities or professional agricultural organisations to apply for mutual recognition of product authorisations in those other Member States so that farmers situated there can also have access to the product concerned. Additionally, the administrative burden for such applicants and also for applicants for the extension of authorisations of products for minor uses is reduced by removing the obligation under Article 42 to provide certain documents as part of the application, as these can be obtained directly from the reference Member State having granted the authorisation for which mutual recognition or extension is sought. Lastly, in order to accelerate access to plant protection products that contain only biocontrol or low-risk active substances, it is clarified that if Member States do not take a decision on an application for authorisation of a product authorised by the reference Member State in the zonal system or by mutual recognition of an authorisation granted by another Member State, the authorisation shall be deemed as having been granted.

Article 51 of Regulation (EC) No 1107/2009 has set out specific provisions to facilitate obtaining authorisations of plant protection products for minor uses. However, in practice, some of the conditions haven proven too restrictive i.e. that extension of an authorisation must be in the public interest or that mutual recognition of an authorisation from another Member State is only possible if that authorisation is also for a minor use. Therefore these restrictions should be removed. Furthermore, the application of Article 51 varies significantly depending on the Member States. A report of the European Minor Use Coordination Facility from 2022[12] stressed the lack of harmonisation and difficulties to make available plant protection products for minor crops, which, although occupying a lower production acreage in Europe compared to major crops, may be high value crops and are important for the environment, farmers/producers, and consumers. Therefore, transparency and sharing of best practices should be increased to achieve more equal access to plant protection products for minor users by all farmers independent of the Member State of establishment. For the same purpose Article 51 is amended to provide for a possibility for the Commission to adopt implementing acts harmonising the procedures for granting extensions of authorisations for minor uses and for authorisations by mutual recognition.

Furthermore, Regulation (EU) 2016/2031[13] aims at preventing the establishment or spreading of pests that would have unacceptable economic, environmental or social impacts in the EU territory including EU agricultural production. The availability of plant protection product authorised uses to apply the provisions of Regulation (EU) 2016/2031 is essential and Member States have repeatedly mentioned difficulties in this regard. Also, EFSA has indicated repeatedly in the relevant pest risk assessments that not being able to prevent such establishment

[12] https://minoruses.eu/media/files/resources/MUCF_MU_Survey_2022_Compiled_Information_final.pdf

[13] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, pp. 4–104, ELI: http://data.europa.eu/eli/reg/2016/2031/oj).

or spreading of pests would lead to a higher use of plant protection products in the medium or long term. Administrative simplifications like a one-zone approach (instead of three zones), and a prioritisation of applications for this kind of purposes would increase the timely availability of plant protection product uses and ensure the possibility to apply the provisions of Regulation (EU) 2016/2031.

Regulation (EC) No 1107/2009 contains specific provisions for the use of basic substances, which are defined as active substances that have primary uses for other purposes than plant protection but are nevertheless useful for farmers for protecting plants against pests. Following their approval under Regulation (EC) No 1107/2009, they can be directly used by farmers without obtaining national authorisations by Member States. However, in practice, certain provisions related to basic substances have proven to be unclear and hinder their availability to farmers, in particular the prohibition that they cannot be substances of concern, cannot be placed on the market as plant protection products or that there must be a primary use for purposes other than plant protection. The ambiguity of some of the current legal provisions on basic substances led to disharmonised implementation across the EU, as became evident in a workshop with Member States organised in 2024. Therefore, the relevant provisions are amended and clarified so that in addition to use, the placing on the market of approved basic substances for plant protection purposes does not require an authorisation by Member States to allow for easier access to basic substances by farmers in a suitable form and with clear instructions for use.

Experience has shown that Member States have developed different interpretations of the provisions related to the placing on the market and use of seeds treated with plant protection products in Regulation (EC) No 1107/2009. In particular, divergent views on whether the sowing of treated seeds constitutes a use of plant protection products has created confusion amongst producers of treated seeds, farmers and competent authorities. Additionally, Member States have different interpretations as to whether the provision on treated seeds cover also other types of plant reproductive materials such as tubers, bulbs, or seed potatoes. The lack of clarity creates barriers for the free circulation of treated seeds and plant reproductive materials and has created disparity between the Member States as regards imports of seeds treated with active substances not approved for use in the EU and their sowing. Therefore, the relevant provisions are clarified, in order to increase harmonisation among Member States. It is also clarified that machinery used for the sowing of treated seeds is not to be regarded as pesticides application equipment in the meaning of Directive 2009/128/EC on the sustainable use of pesticides.

The provisions in Regulation (EC) No 1107/2009 related to the protection of data in test and study reports used in regulatory procedures for the approval of active substances and authorisation of plant protection products had been significantly amended compared to the ones under the repealed Directive 91/414/EEC[14]. Experience has shown that the current patched territorial scope under Regulation (EC) No 1107/2009 (Member State per Member State) creates barriers for the entry to the market of new suppliers of plant protection products and unequal distribution and different costs of plant protection products depending on the size of the Member State's market, thus creating unfair competition between plant protection product manufacturers and farmers. Furthermore, the current data protection regime is highly complex and lacks transparency in terms of when data protection for a given test or study report expires in the different Member States, in particular for studies or tests used for renewals of approvals or review of authorisations. The relevant provisions are therefore amended to install EU-wide territorial scope of data protection and the same length of data protection periods for a given test or study report across the EU to increase transparency and facilitate market access for

[14] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, pp. 1–32, ELI: http://data.europa.eu/eli/dir/1991/414/oj)

alternative suppliers and to increase the availability of plant protection products at comparable costs to farmers independent from the Member States where they are established.

Lastly, transitional provisions are established in order to ensure a smooth transition from the current provisions in Regulation (EC) No 1107/2009 to the amended provisions.

Regulation (EC) No 396/2005[15]: Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides allows the setting and maintaining 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 currently may also include a number of substances with particularly severe hazards that prevent their approval in the EU under Regulation (EC) No 1107/2009.

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. It, therefore, announced to establish a principle that the most hazardous pesticides banned in the EU for health and environmental reasons are not allowed back to the EU through imported products. This concerns the following substances: substances with mutagenic or carcinogenic effects, substances that are toxic for reproduction, substances with endocrine disrupting properties that may cause adverse effect in humans or in non-target organisms, persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT) substances, and very persistent and very bioaccumulative substances (vPvB)[59]. This classification is based on scientific criteria listed in Regulation (EC) No 1107/2009.

The identification of such substances should be based on an evaluation by the European Food Safety Authority (EFSA). Where an evaluation of the hazardous properties of the substance under Regulation (EC) No 1107/2009 is not available, the Commission should ask EFSA for an evaluation under Article 43 of Regulation (EC) No 396/2005.

In addition, the definition of the term "import tolerance" in Article 3(2)(g) of Regulation (EC) No 396/2005 is often misunderstood Therefore, the term import tolerance should be repealed and replaced by a reference to good agricultural practice in a third country. The definition of good agricultural practice in Article 3(2)(a) should be adapted accordingly. .

Point 2 of Article 49 of Regulation (EC) No 396/2005 allows for the continued marketing of products that were placed on the market prior to the applicability of new Maximum Residue Levels (MRLs), provided they complied with the MRLs in force at the time of their placing on the market or placing into storage after production. However, this provision is contingent upon ensuring a high level of consumer protection and, therefore, it is currently not applied across the board in situations of potential health concerns for existing MRLs. In such cases, newly established lower MRLs are also enforced for products already available on the market from the date of applicability of the new MRLs, regardless of the specificities of each case. In such circumstances, the products are withdrawn from the market and destroyed. This situation frequently arises when MRLs, which have been stable and deemed safe over extended periods, undergo reassessment based on revised data requirements and/or updated exposure assessment models.

The impossibility to allow, as a matter of principle, for continued marketing of products that are compliant with earlier applicable MRLs has particularly impacted products with long shelf

[15] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, pp. 1–16, ELI: http://data.europa.eu/eli/reg/2005/396/oj)

lives, some of them with high economic value, such as wine, hops, oils, and berries while others being key in human and animal nutrition, such as cereals, pulses and rice, which not only causes economic losses to producers but also creates food waste, which is undesirable and incompatible with the Union's objective to reduce food loss and waste. Stakeholders have persistently appealed to the Commission for amendments to the Regulation to allow continued marketing of products that were compliant with MRLs applicable at the time of production, even after new lower MRLs are implemented. A more proportionate approach, giving the possibility to consider each specific case is therefore proposed.

Article 16 of Regulation (EC) No 396/2005 provides for a procedure for setting MRLs based on monitoring data instead of the standard requirement of having supporting residue trials. It is used for substances that have not been approved for use in plant protection products in the EU for a long time and may now be regarded as contaminants, for minor dietary components like herbal infusions and honey, and for other particular scenarios where residues persistently remain in plants long after their last application. At present, MRLs established through monitoring data are not granted on a permanent basis and must be reviewed within a specified timeframe not exceeding ten years. Although regular reviews are justified for substances for which it can be expected that the levels of the residues concerned might evolve, for substances that have not been approved for several decades and are now deemed as contaminants due to their persistence in the environment and for which stable residue levels have been recorded over many years, such as DDT, dieldrin, aldrin, hexachlorobenzene, or mercury, a mandatory review after ten years appears disproportionate when considering the costs involved.

There is an existing inconsistency between the terminology employed in Regulation (EC) No 396/2005 and that used within international standards for laboratory analysis to decide whether residues in food commodities can be quantified or not. Regulation (EC) No 396/2005 uses the term "limit of determination (LOD)," whereas the appropriate analytical terminology is "limit of quantification (LOQ)." Both terms refer to the same concept: the lowest residue concentration that can be quantified and reported through routine monitoring using validated control methods. However, within international laboratory analysis standards, "LOD" also serves as the abbreviation for "limit of detection," a distinct limit that is lower than the limit of determination/limit of quantification. This discrepancy concerning the abbreviation "LOD," leads to legal uncertainty among food business operators and laboratories, as they often misinterpret these abbreviations. Therefore, it is proposed to use only the term "limit of quantification (LOQ)".

Regulation (EU) No 528/2012: The completion of the review programme of existing biocidal active substances set out in Article 89 of Regulation (EU) No 528/2012 suffers from major delays. Initiated on 14 May 2000 under Directive 98/8/EC[16], and planned to be completed by 14 May 2010, the review programme had to be extended a first time in 2009 until 14 May

[16] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, pp. 1–63, ELI: http://data.europa.eu/eli/dir/1998/8/oj)

2014[17], a second time in 2013 until 31 December 2024[18], and recently a third time until 31 December 2030[19].

The vast majority of the competent authorities in the Member States have not met the time limits for submitting the draft assessment reports for applications for approval of existing active substances. The main reasons for the delays as identified in the Commission implementation report submitted to the Council and the European Parliament in June 2021[20] are: i) the lack of resources in Member States competent authorities; ii) quality of the original applications and delays by applicants in submitting additional data; iii) complex technical questions on specific dossiers that need to be resolved first; iv) evolution of technical guidance; and v) the adoption of new scientific criteria for determining endocrine disrupting properties[21], which triggered the need for further data and assessments. That implementation report also announced that, instead of a second implementation report, an evaluation of the Regulation (EU) No 528/2012 will start in 2025 with the aim of analysing the fitness of the regulatory system set out in the Regulation. While any fundamental changes to Regulation (EU) No 528/2012 should await the outcome of that evaluation, a few targeted amendments should be enacted earlier to increase the efficiency of its implementation.

Since 2015, the Commission has held regular discussions with experts from the Member States at the meetings of the Commission expert group 'Competent Authorities for Biocidal Products (Regulation (EU) No 528/2012)' (the 'CA meetings')[22], including also stakeholder representatives as observers, and agreements were reached on a number of actions[23] to accelerate the delivery of draft assessment reports for existing active substances. The European Chemicals Agency (ECHA) organised workshops and adopted an action plan on active substances[24]. In 2023, the Commission launched a call for expression of interest[25] by Member States to obtain financial grants to help them achieving progress in the implementation of

[17] 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, ELI: http://data.europa.eu/eli/dir/2009/107/oj).

[18] 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, ELI: http://data.europa.eu/eli/reg_del/2013/736/oj).

[19] 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).

[20] The Commission Report is available at this link: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1623326515401&uri=CELEX%3A52021DC0287 and the Staff Working Document, which presents detailed evidence for the findings outlined in the report, is available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021SC0128&qid=1623670527414

[21] 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).

[22] Register Code E03125 (Register of Commission expert groups and other similar entities).

[23] 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

[24] CA-Feb20-Doc.5.2 - Final - AS Action Plan.doc

[25] *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*

Regulation (EU) No 528/2012. Nine Member States have successfully applied for this grant for biocidal products for a total of around 6.8 million euros.

Despite these actions, on 1 September 2025, only 51% of the work programme of existing active substance was completed, which means that the safety of many active substances contained in biocidal products placed on the market in the Member States under the transitional provisions foreseen in the Regulation (EU) No 528/2012 has not yet been established. On the other hand, as the approvals of active substances are limited in time, renewal procedures for a number of active substances evaluated and approved earlier are already ongoing (for some already for the second time), with each procedure binding resources in the competent authorities that are, as a consequence, not available for the completion of the pending assessments of active substances not yet approved.

In order to give higher priority to the completion of the review programme of existing active substances not yet assessed and enable Member States to dedicate their resources to the related tasks, it is appropriate to set an unlimited duration of the approval of active substances, except for active substances that are approved although they meet the exclusion criteria set out in Article 5(1) of the Regulation (EU) No 528/2012 or the substitution criteria set out in Article 10 as these have properties that are of concern to human or animal health or the environment. Nevertheless, in order to maintain a high level of protection of human and animal health and the environment, it will still be possible to set time limits for approvals if found appropriate in the light of the outcome of the risk assessment prior to a decision on an approval and a possibility is foreseen that the Commission periodically select a number of active substances commensurate with available resources for which a full renewal procedure would be triggered, while also maintaining the possibility to initiate early reviews pursuant to Article 15 of Regulation (EU) No 528/2012.

Regulation (EU) No 528/2012 provides in Chapter VIII that as an alternative to national authorisations of biocidal products and mutual recognition procedures and when certain conditions are fulfilled, companies can obtain a Union authorisation for biocidal products granted by the Commission and valid under the same terms and conditions in the entire EU. The requirement for publication in the EU Official Journal of the complete Commission Implementing Regulation granting a Union authorisation including the Summary of the Products Characteristics in all official languages has proven to be cumbersome, leading to delays, and without added value considering that the whole decision is also disseminated on the ECHA website[26]. The procedure for dissemination of information and transparency of decision adopted by the Commission on Union authorisation is therefore simplified, taking also into account the way authorisation decisions are adopted by the Commission and disseminated in other similar regulatory frameworks[27]. More concretely, the individual decisions will no longer take the form of Commission Implementing Regulations and be published at the EU Official Journal, but will take the form of Commission Implementing Decisions only notified to the applicants, and only summaries of these Decisions should be published at the EU Official Journal for transparency.

Lastly, transitional provisions need to be foreseen in order to ensure a smooth transition from the current provisions in Regulation (EU) No 528/2012 to the amended provisions.

[26] https://www.echa.europa.eu/information-on-chemicals/biocidal-products

[27] 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

Regulation (EC) 1829/2003[28]: The use of fermentation processes[29] to manufacture products is of growing importance in the food and feed sectors and in the bioeconomy at large. The Commission has committed to strengthen the competitiveness of these sectors with different initiatives, including its Communication of March 2024 on *Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU*[30], a *Strategy for European Life Sciences* in February 2025[31].

The European food and feed fermentation sector has voiced concerns about uncertainty of the legal status of food and feed fermentation products manufactured using genetically modified micro-organisms (GMMs), due to unclear terms in the definition of the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed. This concerns cases where the GMM is used in the production process but is removed from the fermentation product, although DNA residues from the genetically modified production strain may be present in the food or feed.

Regulation (EC) No 1829/2003 sets out the rules for the placing on the market of food and feed containing, consisting of or produced from genetically modified organisms (GMOs). Recital 16 of that Regulation clarifies that the Regulation does not apply to food and feed produced 'with' a GMO and specifies that food and feed which is manufactured with the help of a genetically modified processing aid is excluded from its scope. The Commission Report on the implementation of Regulation (EC) No 1829/2003 of 25 October 2006[32] ('Commission 2006 Report') further clarified the status of those products.

However, the detection by enforcement authorities of minute amounts of DNA fragments in food and feed products in recent years due to the use of increasingly sensitive analytical methods has raised questions on the legal framework applicable to those products and led to different enforcement practices by national authorities, including the withdrawal of products from the market in some cases. In turn, this has created legal uncertainty for food and feed business operators as to the legal framework applicable to their products. Therefore, it is necessary to clarify in the legislation the legal status of food and feed produced by fermentation using GMMs not present in the final product but containing traces from the genetically modified production strain.

In order to safeguard the smooth functioning of the internal market as regards food and feed fermentation products obtained with GMMs and to ensure legal certainty for operators, the legal status of such products in the legislation is clarified on the basis of the clarification provided in recital 16 of Regulation (EC) No 1829/2003 and the Commission 2006 Report, by excluding from the definition of 'produced from GMOs' food and feed fermentation products obtained with GMMs used as processing aids.

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28 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p.1, ELI: http://data.europa.eu/eli/reg/2003/1829/oj.

29 Fermentation is a process in which micro-organisms such as bacteria, fungi, yeasts and micro-algae are used to preserve and/or transform raw materials into products, e.g. food and feed.

30 COM(2024) 137 final.

31 COM(2025) 525 final.

32 COM(2006) 626 final.

The definitions of 'processing aid' in the food and feed additives legislation[33] allow for the presence of residues from the processing aid in the final product, as long as those residues are unintentional but technically unavoidable, they do not have any technological effect on the food or the feed and they do not have adverse effects on human or animal health or the environment. Therefore, in order to conclude that a GMM has been used as a processing aid in the production of fermentation food and feed products, it should be demonstrated that the above criteria are met. No viable cells of the GMM production strains should remain in the final product and the presence of residual recombinant DNA should be unintentional but technically unavoidable, have no technological effect on the food or the feed and have no adverse effects on human or animal health or the environment. As regards the latter, the assessment of risks relating to the GMMs used during the production process and any residual recombinant DNA of these GMMs is to be carried out under the relevant food and feed legislation for the specific product (e.g. Regulation (EC) No 1831/2003 on additives for use in animal nutrition, Regulation (EC) No 1332/2008 on food enzymes[34], Regulation (EC) No 1333/2008 on food additives, Regulation (EC) No 1334/2008 on flavourings[35], Regulation (EU) 2015/2283 on novel foods[36]). This clarification in the legislation may be complemented by Commission guidance to assist operators in demonstrating compliance with these criteria for different types of fermentation products falling under different pieces of food and feed legislation.

Regulation (EC) No 1831/2003: Regulation (EC) No 1831/2003 on additives for use in animal nutrition[37] was the subject of an evaluation that was published on 28 February 2024[38], which 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 supporting the effective functioning of the internal market. 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 in particular from the evaluation and subsequent stakeholder feedback: renewal of authorisations, modification of existing authorisations and labelling requirements. The 10-year renewal obligation is seen as too resource-intensive for both operators and authorities, with limited added value for safety, and as a too short period to justify investment costs, while resources could rather be allocated to the development of new

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33 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16, ELI: http://data.europa.eu/eli/reg/2008/1333/oj).

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj).

34 Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97, OJ L 354, 31.12.2008, p. 7.

35 Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, OJ L 354, 31.12.2008, p. 34.

36 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327, 11.12.2015, p. 1.

37 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj)

38 SWD(2024) 46 final

and innovative products. Concerning the 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. As to the 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 burden and costs, and improve legal clarity. They do not alter the fundamental objectives of the Regulation. Safeguards such as the possibility to modify, suspend or revoke authorisations at any time remain in place, ensuring that food and feed safety standards are not compromised. The objective of the proposed simplification and clarification measures is ultimately to achieve improved efficiency of the additives' authorisation system and thereby increased competitiveness of EU feed businesses, including SMEs, positive effects on investments and the development and availability of new innovative feed additives in the EU.

Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004: Regulation (EC) No 852/2004[39] and Regulation (EC) No 853/2004[40] of the European Parliament and of the Council provide for a specific notification procedure to be followed by Member States wishing to adopt national measures adapting the requirements laid down in Annexes II and III to those regulations respectively. These requirements concern the production of traditional products, regions with geographical constraints and measures in relation with structure, layout and equipment. However, those regulations also provide for the possibility for the competent authorities of Member States to authorise certain activities or certain production procedures, which must then be notified to the Commission and the other Member States in accordance with Directive (EU) 2015/1535[41]. The proposal aims at simplifying the procedure of notifications of national measures by requiring the use of a unique notification procedure, that provided for in Directive (EU) 2015/1535. This simplification of procedures would be highly beneficial to subsidiarity and the adoption of national measures adapting Union requirements to local needs, where necessary. The procedure in Directive (EU) 2015/1535 is simpler, and more efficient in terms of transparency, translation and time management, since all Member States have access to the TRIS database.

Regulation (EC) 1099/2009[42]: As regards animal welfare at the time of killing, Member State competent authorities are currently required to transmit annual reports to the Commission on depopulation operations carried out the previous year, in addition to the annual reports submitted under the Official Controls Regulation. Given its limited completeness and lack of comparability, the information provided has proven to be of limited value, when compared to the administrative burden of preparing the report. In addition, Member states annual reports under the Official Controls Regulation cover official controls on the Regulation on the welfare of animals at the time of killing including its provisions concerning depopulation operations,

[39] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/852/oj)

[40] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55, ELI: http://data.europa.eu/eli/reg/2004/853/oj)

[41] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 maying down a procedure for the provision of information in the fields of technical regulations and of rules on Information Society services (OJ L 214, 17.9.2015, p.1, ELI: http://data.europa.eu/eli/dir/2015/1535/oj)

[42] Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, pp. 1–30, ELI: http://data.europa.eu/eli/reg/2009/1099/oj)

and are sufficient to verify compliance with Regulation (EC) No 1099/2009. By withdrawing the obligation to submit a specific annual report on depopulation operations, this omnibus will reduce the administrative burden on Member State competent authorities and the Commission.

Regulation (EC) No 999/2001: Regulation (EC) No 999/2001[43] on transmissible spongiform encephalopathies (TSEs) was adopted in 2001 to address the bovine spongiform encephalopathy (BSE) epidemic through a strict precautionary framework. Since then, the epidemiological situation has drastically improved, with most Member States recognised as having negligible risk.

Therefore, the current rules are no longer proportionate to the current low risk to that disease in the EU. Moreover, the rules are misaligned with the World Organisation for Animal Health's standard, revised in 2023[44] and with recent scientific opinion on the BSE risk posed by ruminant collagen and gelatine derived from bones of the European Food Safety Authority (EFSA), published in 2024[45].

The objective of this proposal, adopted through the simplification omnibus, is to modernise Regulation (EC) No 999/2001 by revising certain Articles, so that to ensure that the control measures of that disease can be updated in swiftly and proportionate manner to remove certain existing unnecessary regulatory and operational burdens for authorities and operators, and remain science-based and aligned with international standards, while continuing to guarantee a high level of protection of public and animal health.

In order to achieve this, the proposal empowers the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union. This empowerment allows the Commission to amend the annexes of Regulation (EC) No 999/2001 and to supplement certain provisions concerning surveillance, specified risk material and products of animal origin. Such delegation ensures timely alignment with evolving scientific knowledge, international standards and the epidemiological situation, while ensuring the rights of scrutiny of the European Parliament and the Council.

Regulation (EU) 2017/625: Article 50(3) of Regulation (EU) 2017/625[46] provides that consignments entering the Union and presented for official controls at the border control posts (BCPs), cannot be split until the required controls have been completed on the entire consignment. It implies that BCPs are not allowed to release the compliant part of a consignment if another part still needs further checks, such as laboratory testing.

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[43] Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, pp. 1–40, ELI: http://data.europa.eu/eli/reg/2001/999/oj)

[44] WOAH revised standards adopted in 2023, https://www.woah.org/en/article/woah-members-adopt-a-revised-standard-on-bse/

[45] https://www.efsa.europa.eu/en/efsajournal/pub/8883

[46] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, pp. 1–142, ELI: http://data.europa.eu/eli/reg/2017/625/oj)

This requirement is particularly detrimental to the plant health sector where phytosanitary certificates can cover consignments consisting of multiple batches of various plants and plant products, for which each individual batch require different type of controls and analyses of varying duration. In the case of perishable products with a limited shelf life, these delays can sometimes lead to spoilage or even complete loss of products that are not subjected to any laboratory analysis. Member States and their stakeholders have consistently called for some flexibility in this area, to avoid unnecessary delays and heavy financial consequences for the operators. Introducing an option of partial clearance for consignments of plants and plant products would solve this issue. In addition, this will not compromise the level of phytosanitary protection of the Union territory as it will not impact the quality and accuracy of official controls.

Therefore, it is considered appropriate to amend Article 50(3) of Regulation (EU) 2017/625 to allow the competent authorities of the BCPs to split consignments of plant and plant products before completing the official controls on the entirety of the consignment, in order to release the parts for which official controls have already been finalised.

Article 93(3) and Article 100(2) of Regulation (EU) 2017/625 provide that EU reference laboratories and national reference laboratories have to include all the methods of laboratory analysis, test or diagnosis within accreditation scope. This requirement created significant challenges for laboratories which are expected to seek accreditation for a very large number of contaminants, pests, methods and matrices, including those for which reference material is not available or which are only rarely applied.

The accreditation is complex and costly process for laboratories. Accrediting all the potential combinations in areas such as of plant health, food contact materials, feed additives and food additives, food enzymes and flavourings poses a heavy burden in terms of time and resources on EU reference and national reference laboratories. 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.

This problem has been repeatedly flagged by the Member States and by EU reference laboratories, such as from the national plant health authorities (during several meetings of the Plant Health section of the Standing Committees on Plants, Animals, Food and Feed, and Chief Officers for Plant Health meetings) or from the JRC responsible for food contact materials and feed additives (during several EU reference laboratories Directors meetings), who underline that the current framework does not sufficiently take into account operational realities.

In order to reduce accreditation and human resources costs for EU reference laboratories and national reference laboratories without affecting the reliability of the analysis results it is appropriate to allow under certain conditions to designate them even if they are not accredited for all laboratory methods.

In accordance with point (e) of Article 37(4), Article 93(3), point (a) and Article 100(2) of Regulation (EU) 2017/625 official laboratories, EU reference and national reference laboratories should operate and be accredited in accordance with standard EN ISO/IEC 17025. Nevertheless, certain biological food safety hazards could be analysed in laboratories accredited by both standards EN ISO/IEC 17025 and similar laboratory standard other than EN ISO/IEC 17025 (e.g. ISO 15189).

In order to avoid duplication of accreditation, reduce costs and increase effectiveness of the competent authorities of the Member States to analyse samples for certain biological food safety hazards it is appropriate to allow under certain conditions for laboratories to be accredited by similar laboratory standards other than EN ISO/IEC 17025.

- **Consistency with existing policy provisions in the policy area**

The proposal is part of a package of measures concerning simplification, aiming at reducing administrative burden and costs for industries.

- **Consistency with other Union policies**

This initiative contributes to simplification and reduction of regulatory burdens for the agrifood sector, as announced in the Vision on Agriculture and Food while maintaining the high standards of protection for the human, animal health and the environment.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

Article 37(2), Article 95 and Article 152(4)(b) of the Treaty establishing the European Community; and

Article 43(2), Article 49, Article 114, Article 168(4)(b) and Article 192(1) of the Treaty on the Functioning of the European Union (TFEU).

- **Subsidiarity (for non-exclusive competence)**

The proposed amendments are adopted at EU level as the Regulations concerned were adopted at EU level before and the intended objectives, therefore, could not be sufficiently achieved at Member State level. To solve the same problems, one action at EU level was considered less costly and more efficient than national measures in 27 Member States. Accordingly, amendments to these Regulations need to be made at EU level.

- **Proportionality**

The initiative does not go beyond what is necessary to achieve the objectives of simplification and burden reduction without lowering the protection of human health and environment.

- **Choice of the instrument**

This proposal for revision is a legislative proposal, as the relevant Regulations to be amended were adopted by co-decision/ ordinary legislative procedure.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

This proposal is accompanied by a Commission staff working document that includes a detailed overview of the positive impacts of the proposed amendments of the relevant provisions of food and feed safety legislation, based on existing data and information gathered during the Call for evidence and the previous analyses.

- **Stakeholder consultations**

The Commission ran a proportionate, targeted consultation to calibrate the Omnibus measures, drawing on ongoing exchanges with Member States and stakeholders, recent evaluations (in particular on pesticides legislation and the feed additives regulation. In addition, the Commission organised a targeted Implementation Dialogue on the biocidal products regulation in July 2025. A Call for Evidence ran from 16 September to 14 October 2025, which gathered 6,440 responses overall. Nearly 6,000 came from citizens, mostly due through semi-automated campaigns, 318 from businesses and their associations, 52 public authorities, 107 from civil society, and 16 from academia. All these stakeholders shared 319 position papers with detailed, technical input. The evidence informed the problem definition, prioritisation of options, and safeguards.

On plant protection products, most directly affected stakeholders backed faster access to effective tools, especially biocontrol, while warning that biologicals are not like-for-like replacements and that farmers need workable, affordable options. Many cited delays, complexity and costs in substance renewal and product authorisations, and asked for clearer, risk-based selection for full renewals, firm timelines and better mutual recognition/minor uses extensions. NGOs and citizens, however, voiced strong concerns about the overall direction of simplification, fearing it could weaken safeguards for health, biodiversity and water protection. They called for maintaining or even strengthening the high level of precaution under the pesticides legislation, phasing down pesticide use, limiting derogations, and avoiding any reduction in oversight of active substances or authorisations. Views on aerial spraying of PPP were similarly split: businesses favour enabling use under harmonised risk-management rules (precision, drift reduction, operator safety), while NGOs, citizens and some Member States warned of potential exposure and drift risks, calling for strict limitations near sensitive sites and robust enforcement. On MRLs, many supported clarifications and fair transitional measures to avoid food waste and economic losses, whereas NGOs and some farmer groups urged a more precautionary stance, i.e. tighter controls on import tolerances for substances not approved in the EU and continued prioritisation of consumer health over trade facilitation.

For the BPR, relevant industry stakeholders and several Member States prioritised completing the review programme and simplifying renewals; most business inputs opposed the 2025 “hard stop” for review-data protection, citing free-rider and investment risks, though a minority warned extensions could dampen competition. NGOs and citizens expressed concern that streamlining could be perceived as deregulation and stressed that any adjustments must not reduce scrutiny of high-risk biocidal products or delay the evaluation of endocrine disruptors and should rather await the results of the full evaluation of the BPR.

Authorities and industry sought legal clarity on GMM-derived fermentation products to harmonise enforcement, while NGOs insisted such products should remain covered by GMO rules, with mandatory risk assessment, labelling and traceability to ensure consumer choice.

Feed additives stakeholders largely supported streamlining, indefinite renewals for non-holder-specific authorisations, and wider use of digital labelling, whereas NGOs called for vigilance to ensure safety and transparency of sustainability claims. Member States welcomed simpler hygiene notifications; several requested rationalising animal-welfare depopulation reporting. Stakeholder input also shows broad support for aligning BSE measures with WOAH standards, provided that risk-based updates do not dilute surveillance. On official controls, operators and authorities backed partial clearance of consignments with harmonised procedures and proportionate laboratory-accreditation flexibilities limited in scope.

Overall, stakeholders favoured risk-proportionate simplification that preserves high health, environmental and consumer protection, underpinned by transparency, independent science, and strong enforcement.

- **Collection and use of expertise**

Different suggestions for clarifying certain provisions of food and feed safety legislation and removing the excessive administrative burden stemming from these provisions have emerged through stakeholders' proposals for simplification. Furthermore, in response and the follow-up of the Call of evidence mentioned above, the Commission received more than 6000detailed position papers from stakeholders, providing additional suggestions, data and costs estimates.

- **Impact assessment**

Given the need to urgently put forward a proposal to address the identified problems in order to reduce administrative burden and excessive costs for businesses it has not been possible to prepare a full impact assessment.

However, following better regulation principles, this proposal is accompanied by a Commission staff working document that includes an analysis of the impacts of the proposed measures, based on existing data and information gathered during the various consultations, written input received from stakeholders and previous analyses.

On the basis of the information available, it is expected that the amendments would entail significant cost savings for industry and for authorities. Most measures, e.g. on biocontrol PPP, biocides, feed additives, would start yielding benefits quickly, while the broader PPP framework simplification, requiring structural changes to renewal and authorisation, will have a longer transition. From 2027, business cost savings are estimated at €330 million annually, rising by a further €127 million per year from 2029 as PPP simplifications take effect. In this mandate, the twelve measures are expected to deliver at least €1 billion in 2027–2029, with an additional €2.32 billion in the next mandate.

Public authorities would also gain substantially: administrative costs are projected to fall by about €333 million per year in 2027–2029, reflecting freed capacity in national authorities, EFSA and the Commission, increasing to roughly €343 million annually once the PPP package is operational in 2030. In total, this amounts to an estimated €2.7 billion reduction in administrative costs over 2027–2034.

- **Regulatory fitness and simplification**

This proposal is part of the commitment of the European Commission to lighten the regulatory burden for people, businesses and administrations in the EU to boost prosperity and resilience of the EU. The proposal is therefore aiming at simplifying provisions of food and feed safety legislation, reducing unnecessary burdens and costs for businesses and authorities, without undermining the protection of human and animal health and the environment.

- **Fundamental rights**

The proposal respects the fundamental rights enshrined in the Charter of Fundamental Rights of the European Union and adheres to the principles recognised therein. The reduction of administrative burden on companies should lead to societal gains in terms of wealth creation, employment and innovation. At the same time, the proposal will not undermine the objective of ensuring a high level of protection of human health and of the environment.

4. BUDGETARY IMPLICATIONS

This initiative will not imply any additional costs for the Commission. The budgetary implications for the European Food Safety Authority (EFSA) are outlined in the attached Financial fiche.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will monitor the implementation and application of the new provisions and compliance with them. Furthermore, the Regulations to be amended by this proposal are subject to regular evaluation of their efficiency, effectiveness in reaching their objectives, relevance, coherence and value added in accordance with better regulation principles. This proposal does not require an implementation plan.

- **Detailed explanation of the specific provisions of the proposal**

- **Regulation (EC) 1107/2009**

This legislative proposal contains several targeted amendments to Regulation (EC) No 1107/2009 to accelerate market access for biocontrol active substances and products containing them, including via a clear definition for their identification under Articles 2 and 3, prioritising the approval/authorisation procedures for such substances and products under Articles 11 and 37, giving the possibility to Member States to grant provisional authorisations for plant protection products containing new biocontrol active substances for which the approval procedure is still ongoing under Article 30, and allowing EFSA to take on the tasks of a rapporteur Member State for the initial risk assessment of an application for approval in order to compensate for the lack of capacity in some Member States under Article 7. Additional resources for EFSA are proposed to take on these new tasks as indicated in the Legislative Financial Fiche.

In order to reduce these difficulties and ensure a more equal access to biocontrol products across all Member States, Articles 3 and 33 are amended so that all Member States are to be considered to be in one zone for applications for authorisation for such products. Considering that plant protection products containing only biocontrol active substances or low-risk active substances are not expected to pose different levels of risk in different Member States, the provisions on zonal authorisation in Article 37 and mutual recognition under Article 42 are reinforced so that authorisations for such products granted by one Member States are recognised by tacit agreement if decisions on applications for zonal authorisation or mutual recognition are not adopted within the prescribed deadline. The obligation to keep records under Article 67 shall not apply to plant protection products containing only biocontrol active substances in order to reduce administrative burdens on farmers using these products.

Considering that most approved active substances have gone through at least one renewal process already and that new active substances are expected to have better toxicological and ecotoxicological properties, Article 5 and 32 are to be amended so that the approvals of active substances and authorisations of products containing them become unlimited in time, except for active substances that are candidates for substitution and those approved under Article 4(7) of Regulation (EC) No 1107/2009 as these have properties that are of concern with regards to human or animal health or the environment, and for active substances for which it has been decided to set time limits for approvals if found appropriate in the light of the outcome of the risk assessment prior to a decision on an approval. Article 18 is amended to provide for a possibility that the Commission and Member States periodically select a number of active

substances in the light of new information and commensurate with available resources for which a full renewal procedure would be triggered, while also maintaining the possibility for ad-hoc reviews already foreseen in Article 21 of Regulation (EC) No 1107/2009.

The criteria for identifying low-risk active substances in Article 22 are simplified to only refer to the intrinsic properties of the active substance and Article 7 is amended so that it is possible to apply for a change of the status of an approved active substance to low-risk.

Article 4(7) is amended to clarify for which substances the derogation can be used and to waive the obligation of the Member States authorising plant protection products containing active substances approved under Article 4(7) to draw up a phasing-out plan.

Article 20(2) is amended to allow for the setting of grace periods when the approval of an active substance is not renewed except for cases where there are immediate and serious concerns for human or animal health or the environment. Article 46 is amended to align the maximum grace period that the Member States can set in case of withdrawals of authorisations with the one set under Article 20(2). The maximum grace period both under Article 20(2) and Article 46 is increased to a maximum of 2 years for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

Article 11 is amended in order to provide the possibility for the Member States to ask for support from EFSA during the preparation of the draft assessment report for an application for approval or renewal of approval, for the assessment of additional information required during the peer review process and for updating the draft assessment report after its initial submission.

Article 36(3) is amended in order to clarify that the last assessment conducted at EU level for an active substance is to be regarded as the 'current scientific and technical knowledge' for the substance.

Article 40 and Article 42 are amended in order to facilitate the mutual recognition process, in particular in case of applications submitted by official or scientific bodies involved in agricultural activities or professional agricultural organisations or application for minor uses extensions. Article 51 is also amended in order to further facilitate minor uses extensions.

Article 3, point 17 and Article 37 are amended providing for a one-zone approach (instead of three zones), and a prioritisation of applications for the purposes of Regulation (EU) 2016/2031.

Article 23 and 28 are amended in order to clarify the status of the basic substances and to allow for their marketing so that the farmers and non-professional users in the EU have equal access to these substances.

Article 49 is clarified by providing explicitly that the sowing of treated seeds constitutes a use of plant protection products and by broadening its scope to plant reproductive material in general and not only treated seeds.

Article 59 is amended to provide for EU-wide territorial scope of the data protection and to simplify its application by Member States and applicants.

Transitional provisions are provided to ensure a smooth transition from the current provisions under Regulation (EC)1107/2009 to the new ones.

- **Regulation (EC) No 396/2005**

Article 3(2) is amended to clarify in point (a) that 'good agricultural practice (GAP)' can relate to a use in the EU or in a third country. As a consequence, the definition of the term "import tolerance" in point (g) is no longer needed and can be removed and in Article 6(4) the term "import tolerances" is replaced by "setting an MRL based on a GAP implemented in a third country". Article 14(2)(e) is amended to set out that no MRLs can be set based on good agricultural practices in third countries or international limits set by Codex Alimentarius, if an active substance is identified as particularly hazardous and consequently does not meet the relevant approval criteria under Regulation (EC) 1107/2009.

New paragraphs are added to Article 14 and Article 18 that provide for the possibility to establish transitional measures allowing the placing or remaining on the market in the Union of products that were compliant with the MRLs applicable at the time their placing on the market or at the time of their placing into storage after production in order to avoid the need for market withdrawal and food waste.

Article 15(1) and Article 16 are amended so that MRLs based on monitoring data are no longer temporary, but permanent. For substances that have not been approved for several decades and are now deemed as contaminants due to their persistence in the environment and for which stable residue levels have been recorded over many years, such as DDT or mercury, a mandatory review after ten years is disproportionate when considering the costs involved. At the same time Article 43 is modified so that the MRLs can be reviewed at any time based on new scientific and technical knowledge which ensures that the MRLs based on monitoring data still could be reviewed, if necessary.

Article 3(2)f is amended so that the term 'Limit of determination (LOD)' is replaced with the term 'Limit of quantification (LOQ)' in order to align the terminology to the one used in international standards for laboratory analysis. Article 10(1)b), 31(1)(b) are amended accordingly to replace the abbreviation 'LOD' with 'LOQ'.

- **Regulation (EU) No 528/2012**

In order to give higher priority to the completion of the review programme of existing active substances, Article 4(1) and Article 12(3) are amended to provide for an unlimited duration of the approval of biocidal active substances, except for active substances that are approved although they meet the exclusion criteria set out in Article 5(1) of Regulation (EU) No 528/2012 or the substitution criteria set out in Article 10 as these have properties that are of concern to human or animal health or the environment. The time limits for approvals can also be limited on case-by-case basis in the light of the outcome of the risk assessment prior to a decision on an approval.

In order to maintain a high level of protection of human and animal health and the environment, Article 13 is amended so that it provides the possibility for the Commission to select a number of active substances for which a full renewal procedure would be triggered.

Article 44 and Article 46 are amended so that the individual decisions on union authorisation no longer take the form of Commission Implementing Regulations, published at the EU Official Journal, but the form of Commission Implementing Decisions only notified to the applicants. Thus, only summaries of these Decisions will be published at the EU Official Journal for transparency which will reduce the time period necessary for the translation and publishing and simplify the process.

Transitional provisions are set in order to ensure a smooth transition from the current provisions in Regulation (EU) No 528/2012 to the amended provisions.

- **Regulation (EC) No 1829/2003**

Article 2, point 10 of Regulation (EC) No 1829/2003 is amended to exclude from the definition of 'produced from GMOs' food and feed fermentation products obtained with GMMs used as processing aids.

- **Regulation (EC) No 1831/2003**

Paragraph 8 of Article 9 is amended in order to provide that authorisations granted for feed additives are valid without a time limit, and no longer for a period of ten years. This amendment aligns with the principle of unlimited authorisation period applicable in other sectors such as food additives or veterinary medicinal products. The paragraph specifies that such authorisation is valid without prejudice to Article 13, which allows to modify, suspend or revoke any authorisation at any time where the safety or efficacy conditions for authorisation are no longer met. A new paragraph 8a is added to provide for a derogation to the unlimited authorisation period as regards additives belonging to the category of coccidiostats and histomonostats, the authorisation of which remaining valid for ten years due to their higher safety risk profile in relation to their antimicrobial nature.

Article 14 concerning the renewal of authorisations is amended to reduce its scope to additives belonging to the category of coccidiostats and histomonostats, as a consequence of the provisions laid down in Article 9(8) and (8a).

Transitional measures concerning the application of the new regime are proposed for additives other than coccidiostats and histomonostats, providing that: authorisations granted under Regulation (EC) No 1831/2003 before the entry into force of the new rules (this omnibus) become valid without a time limit; pending procedures concerning applications for renewal of authorisation that have been submitted before the entry into force of the new rules (this omnibus) must continue to be treated under the previous rules; the new rules do not affect the application of the procedure concerning the treatment of applications for authorisation submitted under Article 10(2) of Regulation (EC) No 1831/2003 ('existing products'); the aim being to ensure that all additives must have been authorised at least once under the rules and procedures set out in Regulation (EC) No 1831/2003 and lastly, should post-market monitoring requirements have been imposed in an authorisation granted before the entry into force of the new rules (this omnibus), any related reports must be submitted to the Commission in accordance with the terms of the authorisation and at the latest by the date of the previously set expiry of the authorisation concerned.

Paragraph 1 of Article 13 concerns cases where EFSA adopts an opinion on whether an authorisation still meets the conditions set out by Regulation (EC) No 1831/2003 either on its own initiative or upon request from a Member State or from the Commission. The paragraph is amended to further specify that, in order to prepare its opinion, EFSA has to take into account scientific and technological developments and may request relevant information and data to the person who was the applicant for the authorisation concerned. In addition, considering that the EFSA's opinion is not triggered by the submission of an application for modification of an authorisation, explicit reference is added to the possibilities for EFSA, referred to in Article 32 and Article 33 of Regulation (EC) No 178/2002, to commission any scientific studies and to collect any data that would be needed to perform a proper assessment.

Paragraph 3 of Article 13 concerns cases where an application for modification of an authorisation is submitted by the holder of that authorisation. A subparagraph is added to provide that where a modification of the name of the authorisation-holder is requested, a notification must be sent to the Commission, accompanied by the relevant data, and that the Register of feed additives is to be adapted accordingly. This aims to avoid the need to adopt a formal regulation concerning such administrative modification, while the name of the authorisation-holder will continue to be publicly accessible through the Register of feed additives, instead of being included in the terms of the authorisation regulation. As a consequence, Article 9(6) and (8) are amended to provide that the name of the authorisation-holder is included in the Register of feed additives and no longer in the regulation granting the authorisation.

A new paragraph 4 is added in Article 13 in order to provide for the possibility for any interested party to submit an application for modification of an authorisation for which there is no specific holder, i.e. for the additives belonging to the current categories of technological, sensory or nutritional additives. The requested modification should aim at extending the specifications or conditions included in the existing authorisation, due to its 'generic', i.e. non-holder specific, nature. This new explicit possibility clarifies and simplifies the procedures applicable where requests are submitted to the Commission in view of adapting the terms of existing non-holder specific authorisations, mirroring the procedure in force for holder-specific authorisations, and will be all the more relevant under the new proposed regime of authorisations without a time limit.

A new paragraph 5 is added in Article 13 to allow the adaptation of existing authorisations with regard specifically to the methods of analysis included therein, in order to take into account scientific and technological developments and in the absence of procedure for renewal of authorisations, which could include such adaptation. The proposed procedure allows the Community Reference Laboratory to submit a new evaluation report to be verified by the Authority before the adoption by the Commission of a regulation on the modification of the authorisation.

Paragraph 1 of Article 16 is amended to introduce a distinction between physical and digital labelling of feed additives and premixtures. While this provision basically requires labelling to be made on a label attached to the packaging or container, it is proposed to provide for a derogation to that principle by allowing digital labelling for certain non-safety related information. This derogation concerns information referred to in points (b) (name and address of the person responsible for the labelling particulars), (d) (approval number, where applicable, of the establishment manufacturing or placing the product on the market) and (g) (batch reference number and date of manufacture) of paragraph 1.

A new paragraph 6 is added in Article 16 to set out basic and clear conditions for the labelling of information by digital means: information to be made available on a physical support to the competent authority upon request; information to be easily and directly accessible, free of charge and information to be made available for a period of two years from the date of placing on the market.

A new paragraph 8 is added in Article 16 to empower the Commission to adopt delegated acts to supplement Regulation (EC) No 1831/2003 by establishing rules to enhance and facilitate digital labelling. The aim is to expand digital labelling possibilities in the future to take technological developments into account and to provide operators with greater flexibility, while preserving the core objective of ensuring safe use of feed additives.

In order to take into account the expansion of the possible labelling means, Article 2(2) is amended by adding a definition for 'labelling' and 'label', in line with the corresponding definitions laid down in Regulation (EC) No 767/2009 which sets out labelling rules concerning feed materials and compound feed.

- **Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004**

Article 13 of Regulation (EC) No 852/2004[47] and Article 10 of Regulation (EC) No 853/2004[48] are amended in order to replace the specific notification procedure by the general TRIS notification procedure under Directive (EU) 2015/1535 of the European Parliament and of the Council[49], as it is simpler, and more efficient in terms of transparency, translation and time management. This simplification of procedures would be highly beneficial to subsidiarity and the adoption of national measures adapting Union requirements to local needs, where necessary.

- **Regulation (EC) No 1099/2009**

Member State competent authorities are currently required by Regulation (EC) 1099/2009 to transmit annual reports to the Commission on depopulation operations carried out the previous year, in addition to the annual reports submitted under the Official Controls Regulation. Given its limited completeness and lack of comparability, the information provided has proven to be of limited value, when compared to the administrative burden of preparing the report. In addition, Member states annual reports under the Official Controls Regulation cover official controls on the Regulation on the welfare of animals at the time of killing, including its provisions concerning depopulation operations, and are sufficient to verify compliance with Regulation (EC) No 1099/2009. By withdrawing the obligation in Article 18, paragraph 4 of Regulation (EC) 1099/2009 to submit a specific annual report on depopulation operations, this omnibus will reduce the administrative burden on Member State competent authorities and the Commission

- **Regulation (EC) No 999/2001**

The proposal introduces targeted amendments to Regulation (EC) No 999/2001 to ensure timely alignment with evolving scientific evidence and international standards.

Articles 5, 6, 8 and 16 are amended to provide technical adaptations empowering the Commission to adopt delegated acts to update the list of rapid tests, surveillance requirements and the list of specified risk material. This ensures proportionate and risk-based monitoring, flexible adaptation of subpopulations and age categories, and alignment with World Organisation for Animal Health standards.

In addition, in Article 16 restrictions on gelatine and collagen derived from ruminant bones are removed, in line with the 2023 WOAH standards and the 2024 EFSA opinion.

In Article 23 and new Article 23b revision refer to the removal of the outdated comitology procedures by empowerment of the Commission to adopt delegated acts to amend annexes and supplement provisions in response to epidemiological developments, scientific knowledge,

[47] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/852/oj)

[48] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55, ELI: http://data.europa.eu/eli/reg/2004/853/oj)

[49] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 maying down a procedure for the provision of information in the fields of technical regulations and of rules on Information Society services (OJ L 214, 17.9.2015, p.1) ELI: http://data.europa.eu/eli/dir/2015/1535/oj

international standards and EFSA opinions, while ensuring scrutiny by the European Parliament and the Council. These changes modernise the framework, simplify procedures, and allow proportionate, science-based and internationally coherent control measures for transmissible spongiform encephalopathies

- **Regulation (EU) No 2017/625**

Article 50(3) of Regulation (EU) No 2017/625 is amended to allow the competent authorities of the border control posts to split consignments of plant and plant products before completing the official controls on the entirety of the consignment, in order to release the parts for which official controls have been finalised while other parts still need further controls. This measure will ensure that official controls are carried out at border control posts without causing unnecessary delay or financial loss for the operators of the plant sector, and without compromising the level of phytosanitary protection of the Union territory.

Articles 41, 93, 100 and 144 of Regulation (EU) No 2017/625 are amended so that the Commission is empowered to adopt delegated acts concerning the cases where, and the conditions under which, laboratories may be designated as official laboratories, national reference laboratories and EU reference laboratories, while not operating and being accredited in accordance with standards EN ISO/IEC 17025 and/or not being accredited for all the methods they use for official controls or other official activities.

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard the Treaty on the Functioning of the European Union, and in particular Article 43(2), Article 49, Article 114, Article 168(4)(b) and Article 192(1)thereof ,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) In its Communication A Vision for Agriculture and Food[50], the European Commission announced a cross-cutting simplification package aimed at reducing unnecessary regulatory burdens while maintaining high standards for food and feed safety, human and animal health, and environmental protection.

(2) Ten legal acts in the area and food and feed safety are amended via this Food and Feed Simplification Omnibus Regulation in order to address certain requirements and procedures which are particularly burdensome for the industry and the competent authorities of the Member States. The targeted amendments aim at rendering the food and feed legislation more efficient and cost-effective for the industry, reduce burdens on the industry and authorities, while at the same time ensuring a high level of protection of human and animal health and of the environment.

(3) Regulation (EC) No 1107/2009[51] sets out the regulatory procedure for approval of active substances and authorisation of plant protection products in the EU. In order to decrease farmers' dependency on plant protection products containing chemical active substances and in line with the announcements in the Communication on the Vision for Agriculture and Food, the availability of sustainable plant protection products including in particular plant protection products which contain biocontrol active substances needs to increase. In order to facilitate the implementation of provisions targeting faster market access for biocontrol active substances and products containing them, biocontrol active substances need to be clearly defined and identified under Regulation (EC) No 1107/2009 and the evaluation of applications for approval of such active substances and for the authorisation of plant protection products containing them should be given priority

[50] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A Vision for Agriculture and Food Shaping together an attractive farming and agri-food sector for future generations, COM/2025/75, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025DC0075

[51] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, pp. 1–50, http://data.europa.eu/eli/reg/2009/1107/oj)

while considering the need to ensure adequate crop protection from existing pests and diseases.

(4) The risk assessment of biocontrol active substances requires specific technical knowledge, and some Member States do not have sufficient experts specialised in this type of assessment. Some applicants for approval of biocontrol active substances face difficulties in finding a rapporteur Member State to obtain approval from. In order to increase capacity for the assessment of new biocontrol active substances, it should be possible for the European Food Safety Authority ("the Authority") to assume the role of the rapporteur Member State for the assessment of applications for approval and the Authority's resources should be increased accordingly.

(5) To accelerate the availability to farmers of plant protection products containing new biocontrol active substances, Member States should have the possibility to grant provisional authorisations for such products for a limited period of time as soon as the draft assessment report for an application for approval has been delivered concluding that the substance can be approved. When the new biocontrol active substances is approved, and in order to avoid unnecessary administrative procedures, it should be possible to transform such provisional authorisations into regular authorisations without the need of reassessment unless the conditions of approval require an amendment of the terms set out in the provisional authorisations.

(6) To reduce burdens on applicants and Member States and to facilitate availability of plant protection products containing only biocontrol active substances or low-risk active substances, all Member States should be considered as one zone for applications for the authorisation of such products. Considering also that plant protection products containing only biocontrol active substances are not expected to pose different levels of risk in different Member States, mutual recognition of authorisations for such products granted by one Member States should be considered as granted by tacit agreement if decisions on applications for mutual recognition are not adopted within the prescribed deadline.

(7) Article 67(1) of Regulation (EC) No 1107/2009 requires that professional users of plant protection products shall, for at least three years, keep records of the plant protection products they use, containing the name of the product, the time and the dose of application, the area and the crop where the plant protection product was used in order to raise the protection of human and animal health and the environment by ensuring the traceability and potential exposure, to increase the efficiency of monitoring and control and to reduce the costs of monitoring water quality. Considering that such information is less relevant for plant protection products containing biocontrol active substances, and in order to reduce the administrative burden for farmers, the obligation to keep records should not apply to plant protection products containing only biocontrol active substances.

(8) Article 22 of Regulation (EC) No 1107/2009 sets out criteria to identify low-risk active substances, referring to hazard-based criteria for the substance set out in point 5 of Annex II and risk-based criteria for the plant protection products containing them set out in Article 47. Implementation of these provisions has proven difficult in practice as at the time of the approval or renewal of approval of active substances it is generally not known whether the criteria related to products in Article 47 can be fulfilled or not. The criteria should therefore be simplified to only refer to intrinsic properties of the active substance. Furthermore, there have been cases where an active substance could not be approved as low-risk because certain elements related to the criteria could not be fully

clarified during the approval or renewal of approval procedure, while further information generated later showed that these are fulfilled. However, there is currently no possibility in Regulation (EC) No 1107/2009 to apply for a change of the status of an approved active substance to low-risk. Such a possibility should, therefore, be introduced.

(9) Certain provisions related to basic substances in Regulation (EC) No 1107/2009 have proven to be unclear and hinder the availability of those substances to farmers, in particular the rules that they cannot be substances of concern, cannot be placed on the market as plant protection product or that there must be a primary use for purposes other than plant protection. The ambiguity of these legal provisions on basic substances has led to disharmonised implementation across the Union. Therefore, the relevant provisions should be amended and clarified so that in addition to use, the placing on the market of approved basic substances for plant protection purposes does not require an authorisation by Member States to allow for easier access to basic substances by farmers in a suitable form and with clear instructions for use. To facilitate market entry by companies wishing to supply products containing approved basic substances, it should also be clarified that data submitted for the approval of a basic substances cannot benefit from data protection.

(10) In order to support a transition towards more sustainable active substances and plant protection products, resources in the Member States dedicated to renewal procedures should be made available for the assessment of applications for new active substances and products. Therefore, approvals for active substances and authorisations for plant protection products containing those active substances should become unlimited in time, except for active substances that are candidates for substitution and those approved under Article 4(7) of Regulation (EC) No 1107/2009 as these have properties that are of concern to human or animal health or the environment. Nevertheless, it should still be possible to set time limits for approvals if found appropriate in the light of the outcome of the risk assessment conducted prior to a decision on an approval and a possibility should be foreseen that the Commission periodically select a number of active substances taking into account the available resources for which a full renewal procedure should be triggered, while also maintaining the possibility for ad-hoc reviews already foreseen in Article 21 of Regulation (EC) No 1107/2009.

(11) Article 4(7) of Regulation (EC) No 1107/2009 provides for a derogation to allow for the approval of active substances not meeting the approval criteria laid down in Article 4 and Annex II where it is necessary to do so because of a serious danger to plant health which cannot be contained by other reasonable means including chemical and non-chemical methods with comparable costs, availability and efficacy, “except for active substances having particularly hazardous properties”. Experience has shown that the drafting of this provision is not clear as regards its scope and should be improved to clarify for which substances such a derogation is possible. In addition, the administrative burdens for Member States authorising plant protection products containing such active substances should be reduced.

(12) In order to support Member States lacking sufficient technical or scientific expertise to complete their tasks as rapporteur Member States within the periods foreseen in Regulation (EC) No 1107/2009, it should be possible for rapporteur Member States to ask for support from the Authority when preparing the draft assessment report for an application for approval or renewal of approval, the assessment of additional information required during an evaluation and updating the draft assessment report after its initial submission.

(13) Following the non-renewal of approval of an active substance, Member States are to withdraw all authorisations of plant protection products containing that active substance and farmers are to stop using those products. In such situations, Member States need time to enact withdrawals of product authorisations and existing stocks of products become waste unless grace periods are foreseen to allow for placing on the market and use of such stocks. In addition, farmers need time to find alternatives for the no-longer authorised products. Article 20 of Regulation (EC) No 1107/2009 provides the possibility in certain cases to set grace periods for placing on the market and use of existing stocks of plant protection products for which authorisations are to be withdrawn. However, the conditions set in Article 20 for when such maximum grace periods can be granted should be amended to allow, in general, the setting of a maximum grace period except for cases where there are immediate and serious concerns for human or animal health or the environment. Additionally, the time limit for grace periods of 18 months is insufficient in cases where there are no alternative plant protection products available on the market in the particular Member State at the time of withdrawal of the authorisations. Therefore, the maximum duration of grace periods that Member States may set should be increased to 3 years so that it allows the Member States enough time to have an alternative plant protection product authorised and to allow the farmers to adapt their crop protection solutions. For the same reasons, the maximum grace periods following withdrawals or amendments of authorisations by Member States set out in Article 46 should be aligned with those set in Article 20.

(14) The requirement for Member States to consider 'current scientific and technical knowledge' in the context of product authorisations has led to some confusion and divergent interpretation among Member State, diverging outcomes of risk assessments, and, as a consequence, unequal access to plant protection products for farmers depending on the Member State of their establishment. The assessment in light of the most recent scientific and technical knowledge should be harmonised.

(15) Regulation (EU) 2016/2031[52] aims at preventing the establishment or spreading of pests that would have unacceptable economic, environmental or social impacts in the EU territory including EU agricultural production. The timely availability of authorised plant protection product uses to apply the provisions of this Regulation is essential. Member States have repeatedly mentioned difficulties in this regard and, therefore, the timely availability of authorised plant protection product uses across all Member States to apply the provisions of Regulation (EU) 2016/2031 should be facilitated.

(16) In order to prevent abuse of the mutual recognition system in the light of divergent fees set by the Member States for obtaining authorisations for plant protection products, application for mutual recognition of a product authorisation should only be possible, if the product for which authorisation by mutual recognition is sought is actually placed on the market in the reference Member State. Furthermore, in cases where companies decide to only apply in certain Member States for authorisation of a plant protection product but not in others, it should be made easier for official or scientific bodies involved in agricultural activities or professional agricultural organisations to apply for mutual recognition of product authorisations in these other Member States by lifting

[52] Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, pp. 4–104, ELI: http://data.europa.eu/eli/reg/2016/2031/oj).

some of the submission requirements. The administrative burden for such applicants and also for applicants for the extension of authorisations of products for minor uses should be reduced by removing the obligation to provide certain documents as part of the application, as these can be obtained directly from the reference Member State having granted the authorisation for which mutual recognition or extension is sought.

(17) Divergent views among Member States on whether the sowing of treated seeds constitutes a use of plant protection products has created confusion amongst producers of treated seeds, farmers and competent authorities. Additionally, there are different interpretations as to whether the provision on treated seeds cover also other types of plant reproductive materials such as tubers, bulbs, or seed potatoes. The lack of clarity creates barriers for the free circulation of treated seeds and plant reproductive materials and at the same time has created disparity between the Member States as regards imports of seeds treated with active substances not approved for use in the EU and their sowing. Therefore, the relevant provisions should be clarified, in order to increase harmonisation among Member States. It should also be clarified that machinery used for the sowing of treated seeds is not to be regarded as pesticides application equipment in the meaning of Directive 2009/128/EC[53] on the sustainable use of pesticides.

(18) Some of the conditions for obtaining authorisations for plant protection products for minor uses set out in Article 51 of Regulation (EC) No 1107/2009 haven proven to be too restrictive and should be removed in order to make more products available to farmers. Furthermore, the implementation of that Article varies significantly across Member States. Therefore, transparency and sharing of best practices should be improved and the Commission should be empowered to adopt implementing acts harmonising the procedures for granting extensions of authorisations for minor uses and for authorisations by mutual recognition in order to achieve more harmonised availability of plant protection products for minor uses.

(19) Experience has shown that the provisions in Regulation (EC) No 1107/2009 related to the protection of data in test and study reports submitted for the authorisation of plant protection products are complex and create barriers for the entry to the market of new suppliers of plant protection products and unequal distribution and different costs of plant protection products depending on the size of the Member States, thus creating unfair competition between plant protection product manufacturers and farmers. Furthermore, the data protection regime lacks transparency in terms of when data protection for a given test or study report expires in the different Member States, in particular for studies or tests used for renewals of approvals or extensions of authorisations for minor uses. The relevant provisions should therefore be amended to install the same length of data protection periods for a given study or test across the EU to increase transparency and facilitate market access for alternative suppliers to increase the availability of plant protection products at comparable costs to farmers independent from the Member States where they are established.

(20) Transitional provisions are necessary in order to ensure a smooth transition from the current provisions in Regulation (EC) No 1107/2009 to the amended provisions.

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[53] 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)

(21) Regulation (EC) No 396/2005[54] sets the procedure for defining maximum residue levels of pesticides in or on food and feed of plant and animal origin. 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. In that respect, the Commission intends to establish the principle that the most hazardous pesticides banned in the EU for health and environmental reasons are not allowed back to the EU through imported products.Furthermore, the term "import tolerance" is often misunderstood. a Therefore, the term import tolerance should be repealed and clarified that the definition of good agricultural practice equally applies to EU and a third country for the setting of MRLs; the definition of good agricultural practice should be amended accordingly.

To establish this principle, it should be made clear that for such substances, MRLs will be set at the limit of quantification (technical zero) and no MRLs based on good agricultural practices in third countries nor Codex maximum limits will be set. The substances concerned should be those that do not meet the relevant approval criteria in Annex II to Regulation (EC) No 1107/2009. Where an appropriate evaluation by the Authority of the hazardous properties of the substance under Regulation (EC) No 1107/2009 is not available, the Commission should ask EFSA for an evaluation under Article 43 of Regulation (EC) No 396/2005.

(22) When lowering MRLs under Regulation (EC) No 396/2005, a reasonable period should be allowed to elapse before the new MRLs become applicable, in order to permit Member States, third countries and food business operators to adapt themselves to the new requirements. It is recognised that fresh products, being perishable, are typically sold and consumed prior to the date of applicability of new MRLs. However, products with extended shelf lives, often processed, may still be on the market when the new lower MRLs become effective. To ensure legal certainty and to prevent unnecessary economic losses for farmers and food business operators, as well as to prevent food waste, it is deemed proportionate that products lawfully placed on the market in the Union before the applicable date of the new measure, and compliant with the MRLs valid at the time of their placing on the market in the Union, should be permitted to remain on the market unless food safety is compromised.

(23) Article 16 to Regulation No 396/2005 sets out the procedure for establishing temporary MRLs based on monitoring data, with a mandatory review scheduled within a specified time frame, not exceeding ten years. However, certain MRLs based on monitoring data pertain to active substances that have not been approved in the Union for several decades, and for which residue levels have remained stable over time. Reviewing such temporary MRLs every ten years imposes an unnecessary burden on Member States, food business operators, and the European Food Safety Authority (EFSA) in terms of data generation and analysis. Given that MRLs can be reviewed at any time under Article 43 of Regulation (EC) No 396/2005, it is appropriate to foresee the establishment of MRLs based on monitoring data on a permanent basis.

(24) The terms 'limit of determination (LOD)' used in Regulation (EEC) No 396/2005 and 'limit of quantification (LOQ)' used in international standards of laboratory analysis have the same meaning. However, the acronym 'LOD' may be confused with 'limit of detection' which has a different meaning. For clarity and to avoid confusion among food

[54] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, pp. 1–16, ELI: http://data.europa.eu/eli/reg/2005/396/oj)

business operators and laboratories, it is appropriate to align Regulation (EC) No 396/2005 with the recognised international terminology.

(25) Regulation (EU) No 528/2012[55] sets out the procedures for approval of biocidal active substances and authorisation and placing on the market of biocidal products. The completion of the review programme of existing biocidal active substances set out in Article 89 of that Regulation is significantly delayed. In order to ensure that Member States can dedicate their resources to the completion of the review programme, it is appropriate to set an unlimited duration for the approval of active substances, except for active substances meeting exclusion or substitution criteria under Articles 5(1) or 10 as these have properties that are of concern to human or animal health of the environment, and for active substances for which time limits of approvals are found necessary in the light of the outcome of the risk assessment conducted prior to a decision on an approval. A possibility should be foreseen that the Commission periodically select a number of active substances in the light of new information and taking into account the available resources for which a full renewal procedure should be triggered, while also maintaining the possibility to initiate early reviews pursuant to Article 15 of Regulation (EU) No 528/2012.

(26) To simplify and accelerate the procedure for adoption and publication of the decisions on the applications for Union authorisation of biocidal products submitted pursuant to Chapter VIII of Regulation (EU) No 528/2012, the individual decisions should no longer take the form of Commission Implementing Regulations and be published at the EU Official Journal, but should take the form of Commission Implementing Decisions to be notified to the applicants, and only summaries of these Decisions should be published at the EU Official Journal for transparency.

(27) Transitional provisions are necessary in order to ensure a smooth transition from the current provisions in Regulation (EU) No 528/2012 to the amended provisions.

(28) Regulation (EC) No 1829/2003[56] regulates the placing on the market of food and feed products produced from genetically modified organisms(GMOs). The applicability of Regulation (EC) No 1829/2003 to food and feed products obtained by fermentation processes using genetically modified micro-organisms (GMMs) as production strain should be clarified, in order to ensure the good functioning of the internal market and provide legal certainty to Member State authorities and food and feed business operators. Where no viable cells of the GMMs used in the production process remain in the final food or feed product and the presence of residual recombinant DNA is unintentional but technically unavoidable and has no technological effect on the food or the feed, the GMM is a processing aid, and the resulting food or feed should be excluded from the scope of that Regulation. The risk assessment concerning any residual DNA present in the final product is carried out under the relevant food and feed legislation for the specific product, as it is also done for conventional micro-organisms.

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[55] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, pp. 1–123, ELI: http://data.europa.eu/eli/reg/2012/528/oj)

[56] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, pp. 1–23, ELI: http://data.europa.eu/eli/reg/2003/1829/oj)

(29) Regulation (EC) No 1831/2003[57] sets out the grounds and procedures for authorisation of feed additives in the Union. It provides that authorisations of feed additives are valid for ten years and are renewable for ten-year periods upon submission of an application in due time. This renewal requirement has proved to generate high administrative and regulatory burden and financial costs for businesses but also for the Authority, the Member States and the Commission involved in the renewal procedure, while adding limited safety value. In order to avoid unnecessary administrative and financial burdens, and thereby making available resources to research, product development and market expansion, the authorisation of feed additives should be granted for an unlimited period of time, except for additives belonging to the category of coccidiostats and histomonostats which should remain under the ten-year authorisation regime due to their antimicrobial nature and their derived higher risk profile. Any modification, suspension or revocation of existing authorisations should continue to be adopted anytime where such authorisations do no longer meet the safety or efficacy conditions set out in Regulation (EC) No 1831/2003, taking into account scientific and technological developments. Article 9 and Article 14 of Regulation (EC) No 1831/2003 should therefore be amended accordingly.

(30) Transitional measures should be provided in order to ensure a smooth transition from the ten-year authorisation regime to the new rule of authorisation without a time limit for feed additives other than coccidiostats and histomonostats. In particular, applications for renewal of authorisation submitted before the date of entry into force of the present Regulation and for which no decision on the renewal has been taken yet at that date should continue to be treated in accordance with the provisions applicable at the time of their submission. Furthermore, the abolishment of the time-limited authorisation should be without prejudice to compliance with any post-market monitoring requirements imposed in an authorisation granted under the previous regime.

(31) The implementation of the procedures for modification of authorisation of feed additives, as laid down in Regulation (EC) No 1831/2003, are in some cases too burdensome or could be improved in terms of clarity and coherence. In particular, requests for modification of the holder of an authorisation should be handled as an administrative change and addressed in the Register of feed additives, rather than be included in the terms of the regulation granting the authorisation. In addition, it would be appropriate to allow interested parties to submit an application to modify a non-holder specific authorisation, as it is already provided for holder-specific authorisations, with a view to possibly expanding the conditions of that authorisation. Furthermore, due to the new unlimited authorisation regime, it is appropriate to establish a specific procedure to modify authorisations in order to adapt the methods of analysis concerning feed additives to scientific and technological developments, on the basis of a report of the Community reference laboratory. Article 13 of Regulation (EC) No 1831/2003 should therefore be amended accordingly.

(32) Regulation (EC) No 1831/2003 lays down the labelling requirements applicable to feed additives and premixtures and requires displaying extensive information on a label in a physical form attached to the packaging or the container. In order to take into account the development of new, digital, communication means, to allow more flexibility in the labelling practices and to reduce burden associated with the printing and update of physical labels by the operators, labelling by digital means should be permitted for some

[57] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj).

information under certain conditions of accessibility and reliability. For the purpose of ensuring safe use of feed additives, all safety-critical information should however remain mandatory on the physical label. The concepts of labelling and label should therefore be properly defined in the context of the requirements for feed additives and premixtures in order to provide legal clarity;. Article 2 and Article 16 of Regulation (EC) No 1831/2003 should therefore be amended accordingly.

(33) In order to keep Regulation (EC) No 1831/2003 in line with technical progress and the digitalisation of the society, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of supplementing the Regulation by establishing rules to enhance and facilitate labelling of feed additives and premixtures by the use of digital means. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[58]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(34) Regulation (EC) No 852/2004[59] sets the hygiene requirements for foodstuffs while Regulation (EC) No 853/2004[60] lays down specific hygiene rules for food of animal origin. Regulations (EC) No 852/2004 and Regulation (EC) No 853/2004 provide for a specific notification procedure to be followed by Member States wishing to adopt national measures adapting the requirements laid down in Annexes II and III to those regulations respectively. This procedure, aiming at informing the Commission and the Member States of the draft measures, is to be used where the Member States wish to adapt certain requirements related to traditional production, regions with geographical constraints or only structure, layout and equipment. In addition, Member States wishing to adapt other requirements of the Annexes are to notify such measures in accordance with Directive (EU) No 2015/1535[61]. The existence of two notifications procedures has proved to be cumbersome and confusing. It would be more efficient to simplify the notification requirements for national measures and to bring them in line with the more general provisions of that Directive. Regulations (EC) No 852/2004 and Regulation (EC) No 853/2004 should be amended accordingly.

(35) Regulation (EC) No 1099/2009[62] establishes minimum rules for the protection of animals at the time of slaughter or killing. Under Article 18(4) of Regulation (EC) No 1099/2009 Member State competent authorities are currently required to transmit specific annual reports to the Commission on depopulation operations carried out the previous year in addition to the annual reports submitted in accordance with Regulation

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58 OJ L 123, 12.5.2016.

59 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/852/oj)

60 Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55, ELI: http://data.europa.eu/eli/reg/2004/853/oj)

61 Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 maying down a procedure for the provision of information in the fields of technical regulations and of rules on Information Society services (OJ L 214, 17.9.2015, p.1, ELI: http://data.europa.eu/eli/dir/2015/1535/oj)

62 Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, pp. 1–30, ELI: http://data.europa.eu/eli/reg/2009/1099/oj)

(EU) No 2017/625 on official controls and other official activities[63]. The objective of Regulation (EC) No 1099/2009 is to protect animals at the time of killing. The annual compliance reports under Regulation (EU) No 2017/625 cover animal welfare during killing, including during depopulation activities, and are sufficient to ensure that the objective of Regulation (EC) No 1099/2009 is met. This overlap provides limited added value and inefficiently diverts the resources of competent authorities from risk management. In addition, the information provided under Regulation (EC) No 1099/2009 has proven to be of limited value since it lacks analysis and comparability, when compared to the administrative burden of preparing the report. This additional reporting obligation should therefore be removed with a view to simplifying the requirements and reducing the administrative burden on Member State competent authorities.

(36) Regulation (EC) No 999/2001[64] lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies provides for a single legal basis for transmissible spongiform encephalopathies in the Union. Article 6 of Regulation (EC) No 999/2001 requires each Member State to carry out an annual monitoring programme for transmissible spongiform encephalopathies based on active and passive surveillance in accordance with Annex III. This Article also specify the minimum animal subpopulations to be covered for bovine spongiform encephalopathy (BSE) monitoring.

(37) During its General Session in May 2023, the World Organisation for Animal Health revised Chapter 11.4 "Bovine Spongiform Encephalopathy" of the Terrestrial Animal Health Code[65] and updated the international standards as regards the bovine populations and the age of such populations to be covered by BSE surveillance.

(38) Article 6 of Regulation (EC) No 999/2001 already provides that, after consultation of the appropriate scientific committee, the age laid down for certain bovine categories may be adapted according to scientific progress under the procedure referred to in Article 24(3). However, in order to reflect evolving international standards and scientific progress, the minimum animal subpopulations to be covered in the monitoring programme should also be subject to adaptation under the same procedure. Article 6 should therefore be amended.

(39) Article 8 of Regulation (EC) No 999/2001 requires that tissues with the greatest BSE infectivity, defined as specified risk material, be removed and disposed of in accordance with Annex V. This Article also specify the minimum list of tissues to be removed from bovine animals and the age limit of the animals affected by such removal. During its

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[63] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, pp. 1–142, ELI: http://data.europa.eu/eli/reg/2017/625/oj)

[64] Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, *OJ L 147, 31.5.2001, http://data.europa.eu/eli/reg/2001/999/oj*

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

General Session in May 2023, the World Organisation for Animal Health revised Chapter 11.4 “Bovine Spongiform Encephalopathy” of the Terrestrial Animal Health Code and updated the international standards as regards the commodities harbouring the greatest BSE infectivity based on the BSE risk category of the country where such commodities are originating.

(40) Article 8 of Regulation (EC) No 999/2001 provides that, after consultation of the appropriate scientific committee, the data relating to the age set out in Annex V may be adjusted in accordance with the procedure referred to in Article 24(3). In order to ensure timely alignment with evolving international standards and scientific knowledge, the list of specified risk material set out in Annex V should also be made subject to adaptation under the same procedure taking into account at least the bovine spongiform encephalopathy risk categories of the country where it originates.

(41) Article 16 of Regulation (EC) No 999/2001 lays down the rules on placing certain products of animal origin on the market, including restrictions on gelatine and collagen derived from ruminant bones. The revised Chapter 11.4 “Bovine Spongiform Encephalopathy” of the Terrestrial Animal Health Code confirms that gelatine and collagen derived from ruminant bones are safe commodities. This conclusion was further supported by the 2024 scientific opinion of the European Food Safety Authority on the BSE risk posed by ruminant collagen and gelatine derived from bones[66]. To reflect both international standards and scientific evidence, the provisions of Article 16 should therefore be amended to remove the existing restrictions on these products.

(42) In order to ensure timely alignment with evolving international standards and scientific knowledge, the list of products of animal origin derived from healthy ruminants that are not subject to restrictions on placing on the market or, if need be, export pursuant to this Article, to Annex VIII, Chapters C and D, and to Annex IX, Chapters A, C, F and G should also be made subject to adaptation under the procedure referred to in Article 24(3).

(43) Article 23a describes the measures which are designed to amend non-essential elements of this Regulation, including by supplementing it, to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(3). In order to achieve the objectives of Regulation (EC) No 999/2001 and ensure timely adaptation to evolving epidemiological situations, scientific knowledge and international standards, the Commission should therefore be empowered to adopt delegated acts in accordance with Article 290 of the Treaty to amend the annexes and to supplement that Regulation. In particular, such delegated acts should cover the approval of rapid and alternative tests, the adaptation of requirements for bovine spongiform encephalopathy monitoring and surveillance, the list of specified risk materials, and the conditions for placing on the market or, where appropriate, export of products of animal origin derived from healthy ruminants. Consequently, Articles 23 and 23a should be amended accordingly, with a new Article 23b being inserted to set out the conditions for exercising the powers of delegation.

[66] EFSA BIOHAZ Panel, Scientific Opinion on the potential BSE risk posed bythe use of ruminant collagen and gelatine in feed for non-ruminant farmed animals. EFSA Journal2020;18(10):6267, 68 pp. https://doi.org/10.2903/j.efsa.2020.6267ISSN: 1831-4732© 2020 European Food Safety Authority

(44) Regulation (EU) No 2017/625[67] establishes rules on the performance of official controls by the competent authorities of the Member States, among others, on animals and goods entering the Union in order to verify compliance with Union agri-food chain legislation. Article 50(3) of Regulation (EU) No 2017/625 allows the splitting of consignments only after the completion of official controls and the finalisation of the Common Health Entry Document (CHED), which implies that a consignment cannot be released until all the necessary checks for that consignment have been completed.

(45) Consignments of goods falling under Article 1(2)(g) of Regulation (EU) No 2017/625 may consist of plants and plant products of different types, classes or descriptions, covered by the same official phytosanitary certificate. Due to the diversity of plants and plant products in the same consignment, each item covered by the same phytosanitary certificate may be subjected to physical checks of various types and durations. In some cases certain items could be released immediately while others need to be detained pending the results of laboratory analysis. In the case of perishable products with a limited shelf life, this situation can sometimes lead to spoilage or even complete loss of products that are not subjected to any laboratory analysis.

(46) To ensure that official controls are carried out at border control posts without causing unnecessary delay or financial loss for the operators, and without compromising the level of phytosanitary protection of the Union territory, Article 50(3) of Regulation (EU) No 2017/625 should be amended to allow the competent authorities of the border control posts to split consignments of plant and plant products before completing the official controls on the entirety of the consignment, in order to enable the release of the parts for which official controls have been finalised.

(47) Regulation (EU) No 2017/625 provides that laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities are to be performed by official laboratories which have been designated as such by the competent authorities of the Member States. Analytical, testing and diagnostic methods should meet state-of-the-art scientific standards and offer sound, reliable and comparable results across the Union. For that purpose, official laboratories shall be assisted by national reference laboratories designated by the Member States, and by EU reference laboratories designated by the Commission.

(48) In accordance with point (e) of Article 37(4), Article 93(3), and point (a) and Article 100(2) of Regulation (EU) No 2017/625 official laboratories, EU reference and national reference laboratories are to operate and to be accredited in accordance with standard EN ISO/IEC 17025. However, certain biological food safety hazards can be analysed in laboratories accredited by either standard EN ISO/IEC 17025 or standard EN ISO 15189. It is therefore necessary to avoid duplication of accreditation, reduce costs and increase effectiveness of the competent authorities of the Member States to analyse samples for certain biological food safety hazards. In view of the continuous

[67] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, pp. 1–142, ELI: http://data.europa.eu/eli/reg/2017/625/oj)

development of the international and European standards, alternative standards to EN ISO/IEC 17025 may be appropriate for the purposes of laboratory accreditation in the future.

(49) In accordance with Article 93(3), point (a) and Article 100(2) of Regulation (EU) No 2017/625, EU reference laboratories and national reference laboratories should include all the methods of laboratory analysis, test or diagnosis within their accreditation scope to ensure high performance. However, accreditation is a complex and costly process, which results in a disproportionate burden especially where the numerous pests, contaminants and matrices imply a high number of testing methods. Accrediting all the potential combinations in areas such as of plant health, food contact materials, feed additives and food additives, food enzymes and flavourings poses a disproportionate burden in terms of time and resources on EU reference and national reference laboratories. Moreover, for official laboratories specific rules were established in these areas under Regulation (EU) No 2021/1353.

(50) The competent authorities and the Commission should therefore be able to designate as EU reference and national reference laboratories those laboratories that are not accredited for all the methods they use for official controls and other official activities provided that certain conditions are fulfilled, and official laboratories, EU reference and national reference laboratories that are accredited in accordance with EN ISO/IEC 17025 or an equivalent laboratory standard defined by a delegated act.

(51) In order to ensure uniform conditions for the implementation of Regulation (EU) No 2017/625, including rules and practical arrangements in respect of designation of official laboratories, EU reference and national reference laboratories, implementing powers should be conferred on the Commission by amending Articles 41, 93, 100 and 144. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1107/2009

Regulation (EC) No 1107/2009 is amended as follows:

1. In Article 2, paragraph (2) is replaced by the following:

> '2. This Regulation shall apply to substances, including biocontrol active substances having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances';

2. Article 3 is amended as follows:

   (a) Point 17 is replaced by the following:

   > '17. ′zone′ means a group of Member States as defined in Annex I.
   > For the purpose of use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, uses that are solely and explicitly needed in order to apply the provisions of Regulation (EU) No 2016/2031 or for plant protection products containing as active substances only biocontrol or low-risk active substances, the zone means all zones defined in Annex I.'

   (b) The following point 35 is added:

‘35. ‘biocontrol active substances’ mean micro-organisms, inorganic substances as occurring in nature, with the exception of heavy metals and their salts or substances of biological origin or produced synthetically that are functionally identical and structurally similar to them, such as

- semiochemicals,
- biological macromolecules or molecules comprised of components thereof,
- substances, including of unknown and variable composition, originating from living organisms or derived by biological processes (e.g. extracts from plant products as defined in Article 3(6) of this Regulation, metabolites produced by micro-organisms)’;

3. In Article 4, paragraph (7) is replaced by the following:

‘By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health or plant production which cannot be contained by other reasonable means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005. [This derogation shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008, as mutagenic category 1A or 1B, carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A, or persistent, bioaccumulating and toxic (PBT), very persistent and very bioaccumulating (vPvB), or that are a persistent organic pollutant (POP) as set out in point 3.7.1 of Annex II.]
Member States may authorise plant protection products containing active substances approved in accordance with this paragraph only when it is necessary to control a serious danger to plant health or plant production in their territory.’;

4. Article 5 is replaced by the following:

‘Article 5
First approval
The first approval shall be unlimited in time except for:
a) active substances that are identified as candidates for substitution in accordance with Article 24;
b) active substances that are approved under Article 4 (7); or
c) active substances for which a limited time of approval is set in accordance with Article 6.’;

5. In Article 7, paragraph (1) is replaced by the following:

‘(1) An application for the approval of an active substance, for an amendment of conditions of approval, or for a change of status for an active substance as identified in the regulation referred to in Article 13(4), shall be submitted by the producer of the active substance to a Member State (the “rapporteur Member State”) together with a summary and a complete dossier as provided for in Articles 8(1) and (2) this Regulation or a scientifically reasoned

justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4 of this Regulation. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002, which shall apply mutatis mutandis.

A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

The application shall be examined by the Member State proposed by the applicant, unless another Member State agrees to examine it.

By way of derogation from the first subparagraph, applications for the approval of biocontrol active substances may be submitted to the Authority which shall assume the duties of the rapporteur Member State.';

6. In Article 11, paragraphs (1) and (2) are replaced by the following:

'1. Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall prepare and submit to the Commission, with a copy to the Authority, a report, referred to as the 'draft assessment report', assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4. The rapporteur Member State shall give priority to the assessment of applications for approval of biocontrol active substances and shall endeavour to deliver the draft assessment report as soon as possible and earlier than 12 months.'

'2. The draft assessment report shall also include where relevant, a proposal to set maximum residue levels.

The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge, and may ask the Authority to provide technical and scientific support during the assessment required for the preparation and delivery of the draft assessment report, during the assessment of the additional information referred to in Article 12(3), and for the preparation of necessary updates of the draft assessment report after its initial submission.';

7. In Article 13, paragraph (4) is replaced by the following:

'4. Approved active substances shall be included in the Regulation referred to in Article 78(3) containing the list of active substances already approved. The Commission shall maintain a list of approved active substances electronically available to the public. This list shall indicate whether an active substance is a biocontrol active substance as set out in Article 3 point 35.';

8. Article 14 is replaced by the following:

'Article 14

Renewal of approval

1. On application, the approval of an active substance with a limited approval period shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

Such renewal of the approval may include conditions and restrictions, as referred to in Article 6.

2. The renewal of approval of active substances shall be unlimited in time except for:

a) active substances that are approved as candidates for substitution in accordance with Article 24,

b) active substances whose approvals are renewed under Article 4(7); or

c) active substances for which a limited time of renewal is set in accordance with Article 6.';

9. Article 18 is replaced by the following:

'Article 18

Work programme

The Commission, in cooperation with the Member States and the Authority and taking into account new information and available resources, may adopt an implementing regulation identifying active substances with unlimited approval that are not biocontrol active substances for which a full renewal procedure is to be conducted. This Regulation, adopted in accordance with the regulatory procedure referred to in Article 79(3) shall list the active substance concerned, the Rapporteur and co-Rapporteur Member States, set a reasonable date for the submission of an application for renewal of approval of the substances concerned and an end date for the approvals that allows for an evaluation of the application and the adoption of a decision on the renewal of approval. Articles 15(2), 16, 19 and 20 shall apply.

The Commission may establish a work programme for the renewal of active substances with limited or unlimited approvals periods grouping together similar active substances setting priorities on the basis of safety concerns for human and animal health or the environment, or the most recent available scientific data, and taking into account, as far as possible, the need for an effective control and resistance management of target pest. That programme may require interested parties to submit all the necessary data to the Member States, the Commission and the Authority within a period provided for in the programme.

The programme shall include the following:

(a) the procedures concerning the submission and assessment of applications for renewal of approvals;

(b) the scope of the assessment to be covered, in particular the necessary data to be submitted, including measures to minimise animal testing, in particular the use of non-animal test methods and intelligent testing strategies;

(c) the periods for submission of such data;

(d) rules on the submission of new information;

(e) period for assessment and decision making;

(f) the allocation of evaluation of active substances to Member States, taking into account a balance in the responsibilities and work to be done among Member States acting as rapporteurs.

Following the renewal of the approval of an active substance in accordance with the paragraphs above, Article 43 shall apply.';

10. In Article 20, paragraph (2) is replaced by the following:

'2. The Regulation referred to in paragraph 1 shall provide for a maximum grace period that the Member States can set which shall not exceed two years for the sale and distribution, and in addition a maximum of one year for the disposal, storage, and use of existing stocks of the plant protection products concerned.

In the case of a withdrawal of the approval or if the approval is not renewed because of immediate and serious concerns for human health or animal health or the environment, the plant protection products concerned shall be withdrawn from the market immediately.';

11. Article 22 is replaced by the following:

'Article 22
Low-risk active substances

1. An active substance complying with the criteria provided for in Article 4 and those in point 5 of Annex II shall be approved as a low-risk active substance.
2. Articles 4 to 21 shall apply. Low-risk active substances shall be listed separately in the Regulation referred to in Article 13(4).
3. The Commission may review and if necessary specify new criteria for approving an active substance as low-risk active substance in accordance with Article 78(1)(a).';

12. Article 23 is be replaced by the following:

'Article 23
Approval criteria for basic substances

1. Basic substances shall be approved in accordance with paragraphs 2 to 6. The approval shall be for an unlimited period and Articles 59 to 62 shall not apply.
For the purpose of this Article, a basic substance is an active substance which fulfils all of the criteria below:
(a) is not a substance of concern or the hazard classification of the substance in accordance with Regulation (EC) No 1272/2008 does not apply to the mixture in which it is approved for use or the risk assessment has demonstrated that there are no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health or unacceptable effects on the environment under the approved conditions of use;
(b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects;
(c) is not predominantly used for plant protection purposes but nevertheless is useful in plant protection
i. either directly or in a product consisting of the substance and, where relevant, a simple diluent, other basic substances and substances necessary to stabilise the product, or
ii. is produced directly from plants or parts of plants after simple preparation,
(d) is not an approved active substance for use in plant protection products at the time of the submission of an application for approval as basic substance and no application for an approval as an active substance is under assessment at that moment.
2. An active substance which falls under the definition of a foodstuff in Article 2 of Regulation (EC) No 178/2002 shall be considered as a basic substance, unless it has an immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health or unacceptable effects on the environment arising from the intended use for plant protection.

By way of derogation from Article 4, a basic substance shall be approved where any relevant evaluations, carried out in accordance with other Union legislation regulating the use of that substance for purposes other than for a plant protection product, show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.

3. By way of derogation from Article 7 an application for the approval of a basic substance shall be submitted by a Member State or by any interested party to the Commission.

The application shall be accompanied by the following information:

(a) any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Union legislation regulating the use of the substance; and

(b) other relevant information on its possible effects on human or animal health or the environment.

4. The Commission shall ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within 3 months of the date of the request.

5. Articles 6 and 13 shall apply. Basic substances shall be listed separately in the Regulation referred to in Article 13(4).

6. The Commission may review the approval of a basic substance at any time. It may take into account the request of a Member State to review the approval.

Where the Commission considers that there are indications that the substance no longer satisfies the criteria provided for in paragraphs 1 to 3 it shall inform the Member States, the Authority and the interested party, setting a period for their comments to be submitted.

The Commission shall ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within three months of the date of the request.

Where the Commission concludes that the criteria referred to in paragraph 1 are no longer satisfied, a Regulation to withdraw or amend the approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3).

7. Products containing exclusively of one or more basic substances, and, where relevant, a simple diluent and substances necessary to stabilise the product, may be labelled as "Products containing (a) basic substance(s) for plant protection" and with clear indications about their allowed use for plant protection.

8. Detailed rules for the implementation of paragraphs 1 to 7 may be established in accordance with the regulatory procedure referred to in Article 79(3).';

13. In Article 28, paragraph (2) is amended as follows:

(a) Point (a) is replaced by the following:

'(a) placing on the market and use of products as defined in Article 23 (7).'

(b) The following point (f) is added:

‘(f) placing on the market and use of seeds and other plant reproductive material treated with plant protection products authorised for that use in at least one Member State.’;

14. Article 30 is replaced by the following:

‘Article 30

Provisional authorisations for plant protection products containing biocontrol active substances

1. By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding five years, the placing on the market of plant protection products containing one or more biocontrol active substances not yet approved, provided that:

(a) the dossier(s) is admissible in accordance with Article 9 and pursuant to Article 11 the Rapporteur Member State has finalised the draft assessment report in accordance with Article 11 concluding that the not yet approved biocontrol active substances in the plant protection product are expected to satisfy the requirements of Article 4(2) and Article 4(3);

(b) the Member State concludes that all active substances in the plant protection product comply with the criteria of point 5 of Annex II or qualify as biocontrol active substance and that the uses of the plant protection product for which provisional authorisations are granted satisfy the requirements of Article 29(1)(b) to (h) ;

(c) where relevant, maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.

2. When a Member State grants a provisional authorisation in accordance with paragraph 1, that Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, providing at least the information listed in Article 57(1).

3. Article 44 applies to provisional authorisations granted in accordance with paragraph 1.

4. Following the approval of an active substance contained in a plant protection product for which a Member State has granted a provisional authorisation in accordance with this Article, the Member States may transform the provisional authorisation in a regular authorisation granted in accordance with the provisions of Article 36 without the need for re-examining the authorisation, unless the conditions set in the approval require terms of authorisation different from those set in the provisional authorisation.’;

15. In Article 32, paragraph (1) is replaced by the following:

‘1. The period of authorisation shall be laid down in the authorisation.

Authorisations shall be for an unlimited time if the plant protection product concerned contains only active substances, safeners, and synergists with unlimited approval period, and it has been assessed according to this Regulation considering the latest assessments underlying the approvals of the active substances, safeners, and synergists contained in the product.

Without prejudice to Article 44, the duration of an authorisation shall be set for a period not exceeding 1 year from the date of expiry of the approval of the active substances, safeners and synergists contained in the plant protection

product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved.
This period shall allow the examination as provided for in Article 43 to be carried out.';

16. In Article 33, paragraph (2), point (b) replaced by the following:

'(b) a proposal as to which Member State the applicant expects to evaluate the application in the zone concerned. In the case of an application for use in greenhouses, as post-harvest treatment, for treatment of empty storage rooms and for seed treatment, for uses that are solely and explicitly needed in order to apply the provisions of Regulation (EU) No 2016/2031 and for a plant protection product containing as active substances only biocontrol or low-risk active substances, only one Member State shall be proposed, which evaluates the application taking account of all zones. In this case the applicant shall send the summary or complete dossier as referred to in Article 8 to other Member States on request.';

17. In Article 36, paragraph (1), first subparagraph is replaced by the following:

'1. The Member State examining the application shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application. For the active substances, safeners and synergists contained in the plant protection product, Member States shall rely on the last assessment conducted at EU level in relation to their approval. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment. Where a Member State considers that the last assessment conducted at EU level needs to be updated in the light of new scientific and technical knowledge, it shall inform the Commission as provided for in Article 18 or Article 21.';

18. Article 37 is amended as follows:

(a) paragraph (4) is replaced by the following:

'4. The other Member States concerned shall at the latest within 120 days of the receipt of the assessment report and of the copy of the authorisation of the Member State examining the application decide on the application as referred to in Article 36(2) and (3). Where the application concerns a plant protection product containing as active substances only biocontrol or low-risk active substances and the Member States concerned have not adopted a decision after 120 days, the authorisation shall be deemed as having been granted by the Member States.';

(b) new paragraphs 5 and 6 are added:

'5. The Member State examining the application shall give priority to the processing of applications for plant protection products containing as active substances only biocontrol active substances and shall endeavour to decide as early as possible and in any case within 12 months.
6. The Member State examining applications for plant protection product uses that are solely and explicitly needed in order to apply the provisions of Regulation (EU) 2016/2031 shall endeavour to decide as early as possible and in any case within 6 months.';

19. Article 40 is replaced by the following:

‘Article 40

Mutual recognition

1. The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure, provided for in this subsection, in the following cases:

(a) the authorisation was granted by a Member State (reference Member State) which belongs to the same zone and the authorised plant protection product is placed on the market in the reference Member State;

(b) the authorisation was granted by a Member State (reference Member State) which belongs to a different zone provided that the authorisation for which the application was made is not used for the purpose of mutual recognition in another Member State within the same zone and the authorised plant protection product is placed on the market in the reference Member State;

(c) the authorisation was granted by a Member State for use in greenhouses, as post-harvest treatment, for treatment of empty rooms or containers used for storing plant or plant products, for seed treatment, for uses that are solely and explicitly needed in order to apply the provisions of Regulation (EU) 2016/2031 or for plant protection products containing as active substances only biocontrol active substances regardless of the zone to which the reference Member State belongs and the authorised plant protection product was placed on the market in the reference Member State.

2. Where a plant protection product is not authorised in a Member State because no application for an authorisation has been submitted in that Member State, official or scientific bodies involved in agricultural activities or professional agricultural organisations may apply for an authorisation for the same plant protection product, the same use and under the same agricultural practices in that Member State under the mutual recognition procedure referred to in paragraph 1.’;

20. Article 42 is replaced by the following:

‘Article 42

Procedure

1. The application shall be accompanied by the following:

(a) a copy of the authorisation granted by the reference Member State as well as a translation of the authorisation into an official language of the Member State receiving the application;

(b) a formal statement that the plant protection product is identical to that authorised by the reference Member State;

(c) a complete or summary dossier as required in Article 33(3) when requested by the Member State;

(d) an assessment report of the reference Member State containing information on the evaluation and decision on the plant protection product.

Points (c) and (d) shall not apply for applications submitted under Article 40(2) and Article 51(7).

2. The Member State to which an application under Article 40 is submitted shall decide on the application within 120 days. Where the application concerns a plant protection product containing as active substance only biocontrol or low-risk active substances and the Member State has not adopted a decision after 120 days, the authorisation shall be deemed as having been granted by the Member State.

3. Where requested by the Member State, the applicant shall submit the application in the national or official languages of that Member State or one of those languages.

4. Detailed rules for the implementation of this Article may be established in accordance with the regulatory procedure referred to in Article 79(3).';

21. Article 46 is replaced by the following:

'Article 46
Grace period

1. Where a Member State withdraws or amends an authorisation or does not renew it, it may grant a grace period for the disposal, storage, placing on the market and use of existing stocks.

2. Where the reasons for withdrawal, amendment or non-renewal of the authorisation are related to renewal of an approval with conditions and restrictions, non-renewal of approval under Article 20(1), or withdrawal of approval under Article 21(3), the grace period shall not exceed the maximum set under Article 20(2).

3. In all other cases, the grace period shall be limited and shall not exceed 2 years for the sale and the distribution and an additional maximum of 1 year for the disposal, storage, and use of existing stocks of the plant protection products concerned.';

22. Article 49 is replaced by the following:

'Article 49
Placing on the market of treated seeds and plant reproductive material

1. The treatment of seeds and plant reproductive material with plant protection products as well as the sowing of the treated seeds and plant reproductive material constitutes a use of plant protection product. Placing on the market and use of seeds and plant reproductive material treated with a plant protection product which is not authorised in any Member State is prohibited.

2. Member States can only prohibit placing on the market or the use of seeds and plant reproductive material treated with plant protection products authorised for that use in at least one Member State if there are substantial concerns that treated seeds are likely to constitute a serious risk to human or animal health or to the environment and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned. The Commission shall take measures to restrict or prohibit the use and/or sale of such treated seeds in accordance with the regulatory procedure referred to in Article 79(3). Before taking such measures the Commission shall examine the evidence and may request an opinion from the Authority. The Commission may set a time limit within which such an opinion shall be provided.

3. Articles 70 and 71 shall apply.

4. Without prejudice to other Union legislation concerning the labelling of seeds, the label and documents accompanying the treated seeds shall include the name of the plant protection product with which the seeds were treated, the authorisation number and the Member State which authorised it, the name(s) of the active substance(s) in that product, standard phrases for safety precautions as provided for in Regulation (EC) No 1272/2008 and risk mitigation measures set out in the authorisation for that product where appropriate.

5. Machinery used to sow treated seeds shall not be considered pesticide application equipment in the context of Article 8 of Directive 2009/128.';

23. Article 51 is replaced by the following:

'Article 51

Authorisations for minor uses

1. The authorisation holder, official or scientific bodies involved in agricultural activities, professional agricultural organisations or professional users may ask for the authorisation of a plant protection product already authorised in the Member State concerned to be extended to minor uses not yet covered by that authorisation.

2. Member States shall extend the authorisation provided that all the following conditions are met:

(a) the intended use is minor in nature;

(b) the conditions referred to in points (b), (d) and (e) of Article 4(3) and Article 29(1)(i) are satisfied;

(c) the documentation and information to support the extension of use has been submitted by the persons or bodies referred to in paragraph 1 or is available otherwise, especially data on the magnitude of residues and where necessary on the risk assessment to the operator, worker and bystander.

3. Member States shall take measures to facilitate or encourage the submission of applications to extend the authorisation of already authorised plant protection products to minor uses.

4. The extension may take the form of an amendment to the existing authorisation or may be a separate authorisation, in accordance with the administrative procedures of the Member State concerned.

5. When Member States grant an extension of authorisation for a minor use, they shall inform if necessary the authorisation holder and request him to change the labelling accordingly.

Where the authorisation holder declines, the Member States shall ensure that users are fully and specifically informed as to instructions for use, by means of an official publication or an official website.

The official publication or where applicable the label shall include a reference to the liability of the person using the plant protection product with respect to failures concerning the efficacy or to phytotoxicity of the product for which the minor use was granted. The minor use extension shall be separately identified in the label.

6. Extensions on the basis of this Article shall be separately identified and separate reference shall be made to liability restrictions.

7. The applicants referred to in paragraph 1 may also apply for authorisation of a plant protection product for minor uses in accordance with Article 40(1)

even if the uses in the reference Member State are not minor uses. Member States shall authorise such uses in accordance with the provisions of Article 41.

8. Member States shall establish and regularly update a publicly available list of minor uses.

9. Detailed rules for the implementation of this Article 51 may be established in accordance with the regulatory procedure referred to in Article 79(3).

10. Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply.';

24. Article 59 is replaced by the following:

'Article 59

Data protection

1. Test and study reports shall benefit from Union-wide data protection under the conditions laid down in this Article.

The protection shall apply to test and study reports concerning the active substance, safener or synergist, adjuvants and the plant protection product as referred to in Article 8(2) when they are submitted to a Member State by an applicant for authorisation under this Regulation, (the first applicant), provided that those test and study reports were:

(a) necessary for the authorisation or an amendment of an authorisation in order to allow the use on another crop; and

(b) certified as compliant with the principles of good laboratory practice or of good experimental practice.

Where a report is protected, it may not be used by any Member State for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and adjuvants, except as provided in paragraph 2 of this Article, in Article 62 or in Article 80.

The period of data protection shall be 10 years starting at the date of the authorisation in the first Member State granting an authorisation based on a dossier including the report, except as provided in paragraph 2 of this Article or in Article 62. That period is extended to 13 years for plant protection products covered by Article 47.

Those periods shall be extended by 3 months for each extension of authorisation for minor uses on a different crop/pest combination as defined in Article 51(1), except where the extension of authorisation is based on extrapolation, if the applications for such authorisations are made by the authorisation holder at the latest 5 years after the date referred to in the preceding sub-paragraph.

The same data protection rules as for the first authorisation shall also apply to test and study reports submitted by third parties for the purpose of extension of authorisation for minor uses as referred to in Article 51(1).

A test or study report shall also be protected if it was necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months from the first renewal/review of authorisation granted in any Member State. The first to fourth subparagraphs shall apply mutatis mutandis.

The total period of data protection may in no case exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may in no case exceed 15 years.

2. The test and study reports may be used for the benefit of another applicant if:

(a) the applicant has submitted a letter of access; or

(b) where any period of data protection granted for the test and study reports concerned in relation to another plant protection product under this regulation has expired.

3. Data protection under paragraph 1 shall only be granted where the first applicant has claimed data protection for test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product at the time of submitting the dossier and has provided to the Member State concerned for each test or study report the information referred to in point (f) of Article 8(1) and in point (d) of Article 33(3) as well as confirmation that a period of data protection has never been granted for the test or study report anywhere in the Union or that any period granted has not expired.

4. Detailed rules for the implementation of this Article may be established in accordance with the regulatory procedure referred to in Article 79(3).';

25. In Article 67, paragraph (1) is replaced by the following:

'1. Producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, except for plant protection products containing as active substances only biocontrol active substances, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used. They shall make the relevant information contained in these records available to the competent authority on request. Third parties such as the drinking water industry, retailers or residents, may request access to this information by addressing the competent authority.'.

Article 2

Transitional provisions concerning Regulation (EC) No 1107/2009

1. For all active substances, safeners or synergists approved at the date of entry into force of *[OP: please insert the reference of this Regulation]*, approvals shall be deemed unlimited in time, except for:

(i) active substances that are identified as candidates for substitution in accordance with Article 24;

(ii) active substances that are approved under Article 4 (7) or

(iii) active substances for which the submission of application for renewal under Article 15(1) was required before the date of entry into force of *[OP: please insert the reference of this Regulation]* and was not submitted.

The Commission shall amend the Regulation referred to in Article 13(4) of Regulation (EC) No 1107/2009 in accordance with this paragraph.

2. For active substances, safeners or synergists, for which an application for renewal of approval has been submitted before the entry into force of [this Regulation No.. official journal to complete], the procedures shall be completed in accordance with the relevant provisions in Articles 16 – 20 of Regulation (EC) No 1107/2009.

3. In case where all applications for renewal of approval of an active substance, safener or synergist are withdrawn during the procedure, a Regulation to withdraw the

approval shall be adopted in accordance with the regulatory procedure referred to in Article 79(3) of Regulation (EC) No 1107/2009.

4. Article 43 of Regulation (EC) No 1107/2009 shall apply for the renewal of authorisations of plant protection products containing active substances, safeners or synergists referred to in paragraph 1 and 2 above. Any ongoing procedures under Articles 33, 34, 42, 44 of that Regulation which started before the entry into force of [this Regulation No.. official journal to complete] shall be finalised following the legal provisions in force before their amendment.

5. Article 59 of Regulation (EC) No 1107/2009 as amended by [this Regulation No.. official journal to complete] shall apply for data protection periods that start after the entry into force of that Regulation. All data protection periods for test and study reports submitted for plant protection products authorisations which started before the entry into force of [this Regulation No.. official journal to complete] shall end 13 years after the first plant protection product authorisation in any Member State and respectively 30 months after the first plant protection product renewal in any Member State. In any case any data protection which started before the entry into force of *[OP: please insert the reference of this Regulation]* shall end on 1 January 2037.

6. Article 23 of Regulation (EC) No 1107/2009 as amended by *[OP: please insert the reference of this Regulation]* shall apply to all applications for approval of basic substances that were submitted before the entry into force of that Regulation and for which no decision on their approval is adopted before the entry into force of that Regulation, with the exception of the amended provision of Article 23(1)d) of Regulation (EC) No 1107/2009 which shall apply also to already approved basic substances rendering their dual use as basic substance and as active substance in plant protection product possible.

7. Detailed rules for the implementation of the transitional provisions may be established in accordance with the regulatory procedure referred to in Article 79(3) of Regulation (EC) No 1107/2009.

Article 3

Amendments to Regulation (EC) No 396/2005

Regulation (EC) No 396/2005 is amended as follows:

1. In Article 3, paragraph (2) is amended as follows:

(a) point a) is replaced by the following:

‘a) good agricultural practice’ (GAP) means the recommended, authorised or registered safe use of plant protection products under actual conditions at any stage of production, storage, transport, distribution and processing of food and feed. It also implies the application, in conformity with Regulation (EC) 1107/2009 and Directive 2009/128/EC, of the principles of integrated pest control in a given climate zone, as well as using the minimum quantity of pesticides and setting MRLs/temporary MRLs at the lowest level which allows the desired effect to be obtained. The GAP can either be a use in the Union or a use in a third country;’;

(b) point (f) is replaced by the following:

‘(f) ‘limit of quantification’ (LOQ) means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods;’;

(c) point (g) is deleted;

2. In Article 6, paragraph (4) is replaced by the following:

‘4. Applications for setting an MRL based on a GAP implemented in a third country shall be submitted to rapporteur Member States designated pursuant to Regulation (EC) 1107/2009. If no such rapporteur has been designated, applications shall be made to Member States designated by the Commission in accordance with the procedure referred to in Article 45(2) of this Regulation at the request of the applicant. Such applications shall be made in accordance with Article 7 of this Regulation.’;

3. In Article 10, paragraph (1), point (b) is replaced by the following:

‘(b) the anticipated LOQ for the pesticide/product combination;’;

4. Article 14 is amended as follows:

(a) In paragraph (2), point (e) is replaced by the following:

‘(e) a CXL or a GAP implemented in a third country for the legal use of an active substance in that country. In case the active substance does not meet the criteria set out in points 3.6.2 to 3.6.5, 3.7.1 to 3.7.3, and 3.8.2 of Annex II to Regulation (EC) No 1107/2009 according to the latest available evaluation under Regulation (EC) No 1107/2009 and/or a specific evaluation in accordance with Article 43 to Regulation (EC) No 396/2005, a MRL based on a CXL or a GAP implemented in a third country cannot be established and the level established according to Article 18(1)(b) applies. ’;

(b) A new paragraph 2a is inserted:

‘2a. Where it is necessary in order to allow for the normal marketing, processing and consumption of products, the regulations implementing MRLs provided for in Articles 15 and 16 and adopted in accordance with the procedure referred to in Article 45(2), may establish appropriate transitional measures allowing the placing or remaining on the market in the Union of products that were compliant with the MRLs applicable at the time of their placing on the market or at the time of their placing into storage after production.
The burden of proving when the products were placed on the market or placed into storage after production shall be borne by the food business operator.’

5. In Article 15, paragraph (1), point (c) is deleted.

6. Article 16 is replaced by the following:

‘Article 16
Procedure for setting MRLs in certain circumstances
1. The Commission may adopt a Regulation under Article 14(1) setting a MRL to be included in Annex III in the following circumstances:
(a) in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of plant protection products pursuant to Regulation (EC) 1107/2009; or

(b) where the products concerned constitute a minor component of the diet of consumers, and do not constitute a major part of the diet of relevant subgroups, and, where relevant, of animals; or

(c) for honey; or

(d) for herbal infusions; or

(e) where essential uses of plant protection products have been identified by a Decision to delete an active substance from, or not to include an active substance in, Annex I to Directive 91/414/EEC; or

(f) where new products, product groups and/or parts of products have been included in Annex I, and one or more Member States so request, in order to allow any scientific studies necessary for supporting an MRL to be undertaken and evaluated, provided that no unacceptable safety concerns for the consumer have been identified.

2. The inclusion of MRLs as referred to in paragraph 1 shall be based on the opinion of the Authority, monitoring data and an assessment demonstrating that there are no unacceptable risks to consumers or animals.'

7. In article 18, a new paragraph (1a) is inserted:

'1a. Where it is necessary in order to allow for the normal marketing, processing and consumption of products, the regulations implementing MRLs provided for in Articles 15 and 16 and adopted in accordance with the procedure referred to in Article 45(2), may establish appropriate transitional measures, allowing the placing or remaining on the market in the Union of products that were compliant with the MRLs applicable at the time of their placing on the market or at the time of their placing into storage after production .

The burden of proving when the products were placed on the market or placed into storage after production shall be borne by the food business operator.;

8. In Article 31, paragraph (1), point(b) is replaced by the following:

'(b) the LOQs applied in the national control programmes referred to in Article 30 and under the Community control programme referred to in Article 29;';

9. Article 43 is replaced by the following:

'Article 43

Review of maximum residue levels and scientific opinion of the Authority

The Commission may review maximum residue levels established under this Regulation at any time in the light of new scientific and technical knowledge. The Commission or the Member States may request from the Authority a scientific opinion on any measure related to the assessment of risks under this Regulation. The Commission may specify the time limit within which such an opinion shall be provided.'.

Article 4

Amendments to Regulation (EU) No 528/2012

Regulation (EU) No 528/2012 is amended as follows:

1. In Article 4, paragraph (1) is replaced by the following:

‘1. An active substance shall be approved if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5).

Approvals shall be unlimited in time except for active substances that are identified as candidates for substitution in accordance with Article 10 or where the conditions of approval set in accordance with paragraph 3 of this Article establish a limited time of approval. An active substance that falls under Article 5 may only be approved for an initial period not exceeding five years.’;

2. In Article 12, paragraph (3) is replaced by the following:

‘3. The renewal of an approval of an active substance shall be for an unlimited time for all product-types to which the approval applies, unless the active substance is identified as candidate for substitution in accordance with Article 10 or a shorter period is specified in the implementing regulation adopted in accordance with point (a) of Article 14(4) renewing such an approval.’;

3. In Article 13, paragraph (1) is amended as follows and a new paragraph is added:

‘1. Applicants wishing to seek renewal of the approval of an active substance with a limited time of approval for one or more product-types shall submit an application to the Agency at least 550 days before the expiry of the approval. Where there are different expiry dates for different product-types, the application shall be submitted at least 550 days before the earliest expiry date.

1a. The Commission may adopt an implementing decision in accordance with the examination procedure referred to in Article 82(3) identifying active substances with unlimited approval for which a full renewal procedure shall be conducted, taking into consideration new information and available resources. The decision shall list the active substance concerned and set a reasonable date for the submission of an application for renewal of approval of the substances concerned and an end date for their approvals that allows for an evaluation of the application and the adoption of a decision on the renewal of approval.’;

4. In Article 44, paragraph (5), the first subparagraph is amended as follows and a new subparagraph is added:

‘1. On receipt of the opinion of the Agency, the Commission shall adopt either an implementing decision granting the Union authorisation of the biocidal product or an implementing decision stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Summaries of Commission decisions shall be published in the Official Journal of the European Union, indicating in particular the decision number, the nature of the decision, the name of the biocidal product, the active substance(s) contained in the biocidal product, the product type(s), the authorisation number, the authorisation holder, the expiry date of the authorisation, as well as indicating a reference to the publication by the Agency of information in accordance with Article 67(2) and (4) of this Regulation.

The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the

territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1).';

5. In Article 46, paragraph (4), the first subparagraph is replaced by the following:

'On receipt of the opinion of the Agency, the Commission shall adopt an implementing decision renewing the Union authorisation or refusing to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).'.

Article 5

Transitional measures concerning Regulation (EU) 528/2012

1. For all active substances approved under Regulation (EU) 528/2012 at the date of entry into force of this Regulation for one or more product-types, approvals shall be deemed unlimited in time for the concerned product-types, except for active substances that meet the criteria set out in Article 5(1) or Article 10 of Regulation (EU) No 528/2012 and active substances for which no application for renewal was submitted by the deadline set out in Article 13(1) of Regulation (EU) No 528/2012 by the date of entry into application of this Regulation.

The Union list of approved active substances referred in Article 9(2) of Regulation (EU) No 528/2012 shall be updated accordingly.

2. For active substance/product-type combinations for which an application for renewal has been submitted to the Agency at the date of entry into force of this Regulation, the procedures shall be completed in accordance with the relevant provisions in Articles 13 and 14 of Regulation (EU) No 528/2012.

When an applicant withdraws its application after its submission and there is no other application under examination for the same active substance for the concerned product-type(s), the Commission shall adopt a decision cancelling the approval of the concerned active substance for the concerned product-type(s) in accordance with the examination procedure referred to in Article 82(3). Articles 48 and 52 shall apply accordingly.

Article 6

Amendment to Regulation No (EC) 1829/2003

Regulation (EC) 1829/2003 is amended as follows:

In Article 2, point (10), the following is added:

'Food and feed which are produced using genetically modified microorganisms (GMMs) as production strains shall not be considered food and feed 'produced from GMOs', provided that no viable cells of the GMMs remain in the food or the feed and the presence of residual recombinant DNA complies with the criteria for residues in the definition of 'processing aid' in Regulation (EC) No 1333/2008 or Regulation (EC) No 1831/2003. The definition of GMM in Directive 2009/41/EC shall apply, excluding animal and plant cells in culture;'.

Article 7

Amendment to Regulation (EC) No 1831/2003

Regulation (EC) No 1831/2003 is amended as follows:

1. In Article 2, paragraph (2), the following points are inserted:

> ‘(o) labelling’ means the attribution of any words, particulars, trade marks, brand name, pictorial matter or symbol to a feed additive or a premixture by placing this information on any medium referring to or accompanying such feed additive or premixture, such as packaging, container, notice, label, document, ring, collar, the Internet or digital means, including for advertising purposes;
>
> (p) ‘label’ means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on, or attached to the packaging or the container of the feed additive or premixture.’;

2. Article 9 is amended as follows:

   (a) Paragraph (6) is replaced by the following:

> ‘6. A Regulation granting authorisation for additives consisting of, containing or produced from GMOs shall include, where appropriate, the unique identifier attributed to the GMO as referred to in Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (1).(1) See page 24 of this Official Journal.’;

   (b) Paragraph 8 is replaced by the following:

> ‘8. The authorisation granted in accordance with the procedure laid down in this Regulation shall be valid without a time limit throughout the Union, without prejudice to Article 13. The authorised feed additive shall be entered in the Register referred to in Article 17 (hereinafter referred to as the Register). Each entry in the Register shall state the date of authorisation and shall include the particulars referred to in paragraphs 5, 6 and 7of this Article. In addition, each entry in the Register concerning additives belonging to categories (d) and (e) referred to in Article 6(1), and additives consisting of, containing or produced from GMOs, shall include the name of the holder of the authorisation.’;

   (c) The following paragraph 8a is inserted:

> '8a. By way of derogation from paragraph 8, the authorisation granted to additives belonging to category (e) referred to in Article 6(1) in accordance with the procedure laid down in this Regulation shall be valid throughout the Union for 10 years and shall be renewable in accordance with Article 14.’.;

3. Article 13 is replaced by the following:

> 'Article 13
>
> Modification, suspension and revocation of authorisations
>
> 1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out in this Regulation, taking into

account scientific and technological developments. In order to prepare its opinion, the Authority may, where appropriate, request the person who was the applicant for the authorisation concerned, or, where applicable, the holder of the authorisation, to submit within a specified time limit information and data relevant to the assessment. In addition, the Authority may commission any scientific studies necessary and collect any data needed for the assessment in accordance with respectively Articles 32 and 33 of Regulation (EC) No 178/2002. It shall forthwith transmit this opinion to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The opinion shall be made public.

2. The Commission shall examine the opinion of the Authority without delay. Any appropriate measures shall be taken in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002. A decision on the modification, suspension or revocation of an authorisation shall be taken in accordance with the procedure referred to in Article 22(2) of this Regulation.

3. If the holder of the authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States. The Commission shall examine the opinion of the Authority without delay and decide in accordance with the procedure referred to in Article 22(2). If the holder of the authorisation requests a modification of the name of the holder of the authorisation included in the authorisation, a notification to the Commission shall be submitted, accompanied by the relevant data supporting the request for modification and the relevant entry in the Register referred to in Article 17 shall be adapted accordingly.

4. In the case of authorisations not issued to a specific holder, any interested party may submit to the Commission an application for the modification of the terms of the authorisation, accompanied by the relevant data supporting the request for the change. Such modification shall aim to extend the specifications or conditions of the relevant authorisation. The Authority shall transmit its opinion on the request to the Commission and the Member States. The Commission shall examine the opinion of the Authority without delay and decide in accordance with the procedure referred to in Article 22(2).

5. Where, taking account of scientific and technological developments, the Commission, the Community reference laboratory or the Authority considers that the method of analysis included in the Regulation granting an authorisation needs to be modified, a new evaluation report shall be submitted by the Community reference laboratory to the Commission, the Authority and, in the case of additives belonging to categories (d) and (e) referred to in Article 6(1), and additives consisting of, containing or produced from GMOs, to the holder of the authorisation concerned. The Authority shall issue an opinion after verification of the report of the Community reference laboratory and transmit it to the Commission, to the Member States and, where applicable, to the holder of the authorisation. The Commission shall examine the opinion of the Authority without delay and shall decide on the modification of the authorisation concerned in accordance with the procedure referred to in Article 22(2).

6. The Commission shall without delay inform the applicant of the decision taken. The Register shall be amended where appropriate.

7. Articles 7, 8 and 9 shall apply accordingly.';

4. Article 14 is replaced by the following:

'Article 14

Renewal of authorisations

1. Authorisations granted under this Regulation to additives belonging to category (e) referred to in Article 6(1) shall be renewable for 10 year periods. An application for renewal shall be sent to the Commission by the holder of the authorisation or his legal successor or successors, who shall be deemed to be the applicant, at the latest one year before the expiry date of the authorisation.

2. At the time of application, the applicant shall send the following particulars and documents directly to the Authority:

(a) a reference to the current authorisation for placing the feed additive on the market;

(b) a report on the results of the post-market monitoring, if such monitoring requirements are included in the authorisation;

(c) any other new information which has become available with regard to the evaluation of the safety in use of the feed additive and the risks of the feed additive to animals, humans or the environment;

(d) where appropriate, a proposal for amending or supplementing the conditions of the current authorisation, inter alia, the conditions concerning future monitoring.

3. Articles 7, 8 and 9 shall apply accordingly.

4. Where, for reasons beyond the control of the applicant, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. Information on this extension of the authorisation shall be made available to the public in the Register referred to in Article 17.';

5. Article 16 is replaced by the following:

'Article 16

Labelling and packaging of feed additives and premixtures

1. No person shall place on the market a feed additive or a premixture of additives unless a label is attached to its packaging or container under the responsibility of a producer, packer, importer, seller or distributor established within the Community and bears the following information, in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member State in which it is marketed, in relation to each additive contained in the material:

(a) the specific name given to the additives upon authorisation, preceded by the name of the functional group as mentioned in the authorisation;

(b) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this Article. By way of derogation from the first subparagraph, this information may be provided by digital means;

(c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight;

(d) where appropriate, the approval number of the establishment manufacturing or placing on the market the additive or the premixture pursuant to Article 10 of Regulation (EC) No 183/2005 of the European

Parliament and of the Council. By way of derogation from the first subparagraph, this information may be provided by digital means;
(e) directions for use, any safety provisions or recommendations regarding the use and handling of the additive or premixtures mentioned in the authorisation, including animal species and categories for which the additive or premixture of additives is intended, and other specific labelling requirements laid down in the authorisation;
(f) the identification number; the batch reference number and date of manufacture. By way of derogation from the first subparagraph, this information may be provided by digital means.
In the case of premixtures, points (b), (d), (e) and (g) shall not apply to the incorporated feed additives.
2. For flavouring compounds, the list of additives may be replaced by the words 'mixture of flavouring compounds'. This shall not apply to flavouring compounds subject to a quantitative limitation when used in feed.
3. In addition to the information specified in paragraph 1, the label attached to the packaging or container of an additive belonging to a functional group specified in Annex III or of a premixture containing an additive belonging to a functional group specified in Annex III shall bear the information indicated in point 1, point 2(a)(i) and 2(b)(i) of that Annex, as applicable, presented in a conspicuous, clearly legible and indelible manner.
4. In the case of premixtures, the word 'premixture' shall appear on the label. Carriers shall be declared, in the case of feed materials, in compliance with Article 17(1)(e) of Regulation (EC) No 767/2009 of the European Parliament and of the Council, and, where water is used as a carrier, the moisture content of the premixture shall be declared. Only one minimum storage life may be indicated in respect of each premixture as a whole; such minimum storage life shall be determined on the basis of the minimum storage life of each of its components.
5. Additives and premixtures shall be marketed only in closed packages or closed containers which must be closed in such a way that the fastener is damaged on opening and cannot be re-used.
6. The information provided by digital means shall be:
(a) made available on a physical support to the competent authority upon request;
(b) easily and directly accessible, free of charge, through all major operating systems and browsers, without a need to register in advance, to download or install applications or to provide a password, and accessible to all potential users in the Union and competent authorities for control;
(c) made available for a period of 2 years from the date that the additive or premixture was placed on the market, including in the event of the insolvency, liquidation or cessation of activity in the Union of the economic operator that created it.
7. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex III to take technological progress and scientific development into account.
8. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to supplement this Regulation by establishing rules to enhance and facilitate labelling by the use of digital means, <u>including concerning information referred to in paragraphs 1, 3 and 4. Those rules may not concern safety-critical nor essential-use information.</u>'.

Article 8

Transitional measures concerning Regulation (EC) No 1831/2003

1. Authorisations of feed additives other than those belonging to category (e) referred to in Article 6(1) of Regulation (EC) No 1831/2003, that have been granted in accordance with that Regulation before *[OP: please insert the date = date of entry into force of this Regulation]* shall be considered as valid without a time limit, without prejudice to the procedure concerning applications submitted pursuant to Article 10(2) of Regulation (EC) No 1831/2003.

2. Applications for renewal of authorisation submitted to the Commission in accordance with Article 14 of Regulation (EC) No 1831/2003 before *[OP: please insert the date = date of entry into force of this Regulation]* and for which no decision has been taken yet by that date, shall continue to be treated in accordance with the rules applicable before that date.

3. Where post-market monitoring requirements, as referred to in Article 8(4)(c) of Regulation (EC) No 1831/2003, have been imposed in an authorisation granted under that Regulation, the report on the results of the monitoring shall be submitted to the Commission in accordance with that authorisation and at the latest by the date which was set for the expiry of the authorisation before *[OP: please insert the date = date of entry into force of this Regulation]*.

Article 9

Amendment to Regulation (EC) No 852/2004

Regulation (EC) No 852/2004 is amended as follows:

Article 13 is amended as follows:

(a) Paragraph (3) is replaced by the following:

'3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 and 5 of this Article, national measures adapting the requirements laid down in Annex II.';

(b) Paragraph (5) is replaced by the following:

'5. Those national measures shall be notified in accordance with the procedure laid down in Articles 5 and 6 of Directive (EU) 2015/1535. The notification shall:

(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the foodstuffs and establishments concerned;

(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

(d) give any other relevant information.';

(c) Paragraphs (6) and (7) are deleted.

Article 10

Amendment to Regulation (EC) No 853/2004

Regulation (EC) No 853/2004 is amended as follows:

Article 10 is amended as follows:

(a) Paragraph (3) is replaced by the following:

'3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4, 5 and 8 of this Article, national measures adapting the requirements laid down in Annex III.';

(b) Paragraph (5) is replaced by the following:

'5. Those national measures shall be notified in accordance with the procedure laid down in Articles 5 and 6 of Directive (EU) 2015/1535. The notification shall:

(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the foodstuffs and establishments concerned;

(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

(d) give any other relevant information.';

(c) Paragraphs 6 and 7 are deleted.

Article 11

Amendment of Regulation (EC) 1099/2009

In Regulation (EC) 1099/2009 Article 18, paragraphs 4 and 6 are deleted.

Article 12

Amendment to Regulation (EC) No 999/2001

Regulation (EC) 999/2009 is amended as follows:

1. In Article 5, paragraph (3), the third subparagraph is replaced by the following:

'The Commission is empowered to adopt delegated acts in accordance with Article 23b to approve the rapid tests for that purpose and to amend the list set out in Annex X, Chapter C, point 4';

2. Article 6 is amended as follows:

(a) Paragraph (1) is replaced by the following:

'1. Each Member State shall carry out an annual monitoring programme for TSEs based on surveillance in accordance with Annex III.
The Commission is empowered to adopt delegated acts in accordance with Article 23b approving the rapid tests for that purpose. The Commission is

empowered to adopt delegated acts in accordance with Article 23b amending Annex X to list those tests.';

(b) Paragraph (1)a is replaced by the following:

'1a. The annual monitoring programme referred to in paragraph 1 shall cover the animal subpopulations listed in Annex III. The Commission is empowered to adopt delegated acts in accordance with Article 23b to amend the provisions of that paragraph according to scientific progress and after consultation of the European Food Safety Authority.';

(c) In paragraph (1)b, the first sentence is deleted.;

3. Article 8 is amended as follows:

(a) Paragraph (1) is amended as follows:

'1. The specified risk material shall be removed in accordance with Annex V to this Regulation and disposed of in accordance with Regulation (EC) No 1069/2009.
The Commission is empowered to adopt delegated acts in accordance with Article 23b to determine the list of specified risk material referred to in Annex V . Taking into account the different risk categories laid down in the first subparagraph of Article 5(1) and the requirements of Article 6(1a) and (1b) (b) the list of specified risk material in Annex V shall be amended accordingly.
The specified risk material, referred to in first sub-paragraph, shall not be imported into the Union.';

(b) In paragraph (2), the first subparagraph is replaced by the following:

'The Commission is empowered to adopt delegated acts in accordance with Article 23b to approve an alternative test allowing to detect BSE prior to slaughter and to amend the list in Annex X. Paragraph 1 of this Article shall not apply to tissues from animals which have undergone the alternative test, provided that this test is applied under the conditions provided for in Annex V and the test results are negative.';

(c) Paragraph (5) is replaced by the following:

'5. The Commission is empowered to adopt delegated acts in accordance with Article 23b laying down rules providing for exemptions from paragraphs 1 to 4 of this Article, with regard to the date of the effective enforcement of the feeding prohibition provided for in Article 7(1) or, as appropriate for third countries or regions thereof with a controlled BSE risk, with regard to the date of the effective enforcement of the ban of ruminant protein in feed for ruminants with a view to limiting the requirements to remove and destroy specified risk material to animals born before that date in the countries or regions concerned.';

4. Article 16 is amended as follows:

(a) point 1(b) is replaced by the following:

'(b)milk and dairy products, hides and skins, and gelatine and collagen';

(b) in paragraph (7) the first sentence is replaced by the following:

‘7. The Commission is empowered to adopt delegated acts in accordance with Article 23b supplementing this Regulation to adapt the provisions of paragraphs 1 to 6’;

5. Article 23 is amended as follows:

‘1. After consultation of European Food Safety Authority (EFSA) on any question which could have an impact on public health, the annexes shall be amended or supplemented and any appropriate transitional measures shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(3).
2. In accordance with that procedure, transitional measures shall be adopted for a period ending on 1 July 2007 at the latest, to permit the change-over from the current arrangements to the arrangements established by this Regulation.
3. Without prejudice to paragraphs 1 and 2, the Commission is empowered to adopt delegated acts in accordance with Article 23b amending the Annexes. The amendments shall have the aim of adapting the provisions contained in those annexes to the evolution of the epidemiological situation, of the available scientific knowledge, of the relevant international standards, of the available analytical methods for official controls or of the results of controls or studies on the implementation of those provisions and shall take into account the following criteria:
i. where relevant, the conclusions of the available EFSA opinion;
ii. the need to maintain a high level of protection of human and animal health in the Union.’;

6. Article 23a, points (a), (b), (g), (h) and (k) and (m) are deleted.

7. A new Article 23b is inserted:

'Article 23b

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 5(3), Article 6(1) and (1a), Article 8(1), (2), and (5), and Article 16(7) and Article 23 (3) shall be conferred for an indeterminate period of time from the date of the entry into force of this Omnibus].
3. The delegation of powers referred to in Article 5(3), Article 6(1) and (1a), Article 8(1), (2), and (5), and Article 16(7) and Article 23 (3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better-Law-making of 13 April 2016.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 5(3), Article 6(1) and (1a), Article 8(1), (2), and (5), and Article 16(7) and Article 23 (3) shall enter into

force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.'.

Article 13

Amendment to Regulation (EU) No 2017/625

Regulation (EU) 2017/625 is amended as follows:

1. Article 41 is replaced by the following:

'Article 41

Powers to adopt derogations from the condition for the standard applied by the official laboratories and for the mandatory accreditation of all the methods of laboratory analysis, test and diagnosis used by official laboratories.

The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which, competent authorities may designate as official laboratories, in accordance with Article 37(1), laboratories which do not fulfil the conditions referred to in point (e) of Article 37(4) in relation to:

(a) the standards in accordance with which the official laboratories operate and are accredited; and

(b) the accreditation for all the methods they use for official controls or other official activities, provided that such laboratories comply with the following conditions:

i. they operate and are accredited for the use of one or more methods which are similar to and representative of the other methods they use; and

ii. they make regular and significant use of the methods for which they have obtained the accreditation referred to in point (i) ; except, as regards the area governed by the rules referred to in point (g) of Article 1(2), where a validated method for the detection of the particular pests of plants referred to in Article 34(1) and (2) does not exist.';

2. In Article 50, paragraph (3) is replaced by the following:

'3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 56 has been finalised in accordance with Article 56(5) and Article 57, unless requested by the competent authorities in the case of consignments of goods referred in Article 47(1)(c) for the purposes of performing sampling, physical checks and laboratory analysis on only part of a consignment presented at a border control post.';

3. In Article 93, paragraph (4) is replaced by the following:

'4. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which the Commission may designate European Union reference laboratories irrespective of whether the laboratories fulfil the

condition provided for in point (a) of paragraph 3 of this Article in relation to the accreditation standard and the mandatory accreditation of all the methods of laboratory analysis, test and diagnosis.';

4. Article 100 is amended as follows:

(a) paragraph (2) is replaced by the following:
'2. The requirements provided for in point (e) of Article 37(4), Article 37(5), Article 39 and Article 42(1), points (a) and (b) of Article 42(2) and Article 42(3) shall apply to national reference laboratories.';

(b) paragraph 6 is replaced by the following:
'6. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the cases where, and the conditions under which competent authorities may designate national reference laboratories whether or not the laboratories fulfil the conditions provided for in point (e) of Article 37(4) in relation to the standards in accordance with which the laboratories operate and are accredited and the condition provided for in point (a) of Article 37(5) in relation to the accreditation for all the methods of laboratory analysis, test and diagnosis that the laboratories use.';

5. Article 144 is amended as follows:

(a) paragraph (2) is replaced by the following:

'2. The power to adopt delegated acts referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 93(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) shall be conferred on the Commission for a period of five years from 28 April 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.';

(b) paragraph (3) is replaced by the following:

'3. The delegation of power referred to in Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 93(4), 99(2), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.';

(c) paragraph (6) is replaced by the following:

'6. A delegated act adopted pursuant to Articles 18(7) and 21(8), Article 41, Articles 45(4) and 47(3), Article 48, Article 50(4), Article 51, and Articles 53(1), 62(3), 64(2) and (5), 77(1) and (2), 92(4), 99(2), 93(4), 100(6), 101(2), 126(1), 142(1) and (2), 149(2), 150(3), 154(3), 155(3) and 165(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of

that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.'.

Article 13
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1107/2009, Regulation (EC) No 396/2005, Regulation (EU) No 528/2012, Regulation (EC) 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation 1099/2009, Regulation (EC) No 999/2001, Regulation (EC) No 1069/2009, Regulation (EU) 2017/625 as regards simplifying and strengthening food and feed safety requirements

1.2. Policy area(s) concerned

Competitiveness, prosperity and Security

1.3. Objective(s)

1.3.1. General objective(s)

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

1.3.2. Specific objective(s)

Specific objective No

By reducing administrative burdens for both industry and Member State competent authorities, the proposal aims to help EU farmers and the broader food and feed sector become more competitive and to prevent unacceptable impacts on agricultural production. The proposal aims to accelerate access to innovative biocontrol solutions. This will be achieved by tackling procedural inefficiencies and reallocating or increasing resources in Member State authorities and the European Food Safety Authority (EFSA).

1.3.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

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

By making the approval system for active substances more efficient for plant protection products and biocidal products, and in particular speeding up approval for biocontrol active substances by pproviding the possibility for EFSA to act as rapporteur Member State,reduced costs and faster return on investment for companies placing such substances (i.e. products containing them) on the market. Combined with

measures to strengthen mutual recognition of product authorisations, farmers are expected to benefit from access to more crop protection tools.

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

- faster processing of approval applications for biocontrol active substances due to the possibility for EFSA to act as rapporteur Member State

- increased number of authorisations of biocontrol plant protection products in Member States (pending on the willingness of applicants to market in a certain Member State)

1.4. The proposal/initiative relates to:

☐ a new action

☐ a new action following a pilot project / preparatory action[68]

☒ the extension of an existing action

☐ a merger or redirection of one or more actions towards another/a new action

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

Farmers face a shrinking toolbox as older products lose authorisation and new alternatives – in particular biopesticides – are slow to reach the market. Slow approval of biopesticides makes it difficult to reap the competitive benefits of these substances, including on international markets. There are systematic delays in the procedures for approvals and renewals of approvals of active substances, while deadlines laid down in Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market are not met as Member States lack the capacity to process applications on time.

1.5.2. Added value of EU involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this section 'added value of EU involvement' is the value resulting from EU action, that is additional to the value that would have been otherwise created by Member States alone.

Reasons for action at EU level (ex-ante): The Member States are overloaded both with active substance dossiers as well as with plant proteciotn products dossiers. Some Member States lack sufficient resources and/or expertise to process applications for biocontrol active substances thus it's difficult for the applicants to find a Member State willing to take their application which delays the approval procedure and the entry on the market of innovative biocontrol products.

[68] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

Expected generated EU added value (ex-post) The involvement of EFSA is expected to speed up the approval of biopesticides and consequently, to speed up their entry on the market and increase the available tools for the farmers.

1.5.3. Lessons learned from similar experiences in the past

The proposal is based on complaints both from Member States and stakeholders (applicants and farmers) from the delays in the approval/authorisation procedures and on calls for faster and clearer procedures, especially for biocontrol plant protection active substances and products.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

The Food and Feed Safety Simplificaiton Omnibus is part of the cross-cutting legislative simplification package announced in the European Commission's Vision for Agriculture and Food. The aim of the package is to reduce unnecessary regulatory burdens while maintaining high standards for food and feed safety, for human and animal health, and for environmental protection.

1.5.5. Assessment of the different available financing options, including scope for redeployment

The amount required for EFSA to conduct the new tasks will be covered by an increase in the EFSA annual subsidy.

1.6. Duration of the proposal/initiative and of its financial impact

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☐ **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Method(s) of budget implementation planned[69]

☐ **Direct management** by the Commission

– ☐ by its departments, including by its staff in the Union delegations;

– ☒ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated

– ☐ international organisations and their agencies (to be specified)

– ☐ the European Investment Bank and the European Investment Fund

– ☒ bodies referred to in Articles 70 and 71 of the Financial Regulation

– ☐ public law bodies

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees

– ☐ bodies or persons entrusted with the implementation of specific actions in the common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

If more than one budget implementation method is indicated, please provide details in the 'Comments' section.

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[69] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx.

Comments

[…] […]

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

All Union Agencies work under a strict monitoring system involving an internal control coordinator, the Internal Audit Service of the Commission, the Management Board, the Commission, the Court of Auditors and the Budgetary Authority. This system is reflected and laid down in the European Food Safety Authority's (EFSA) founding regulation. In accordance with the Joint Statement on the EU decentralised agencies (the 'Common Approach'), the framework financial regulation (2019/715) and related Commission Communication C(2020)2297, the annual work programme and Single Programming Document of the Authority comprise detailed objectives and expected results, including a set of performance indicators.

The Single Programming Document combines multiannual and annual programming as well as "strategy documents", e.g. on independence. DG SANTE comments through the Authority's Management Board and prepares a formal Commission Opinion on the Single Programming Document. The activities of the Authority will be measured against these indicators in the Consolidated Annual Activity Report.

The European Food Safety Authority will monitor periodically the performance of its internal control system to ensure that data is collected efficiently, effectively and timely and to identify internal control deficiencies, register and assess the results of controls, control deviations and exceptions. The results of the internal control assessments, including significant weaknesses identified and any differences as compared to internal and external audit findings will be disclosed in the Consolidated Annual Activity Report.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

The annual EU subsidy will be transferred to the Authority in accordance with its payment needs and upon its request. The Authority will be subject to administrative controls including budgetary control, internal audit, annual reports by the European Court of Auditors, the annual discharge for the execution of the EU budget and possible investigations conducted by OLAF to ensure, in particular, that the resources allocated to the Authority are put to proper use. Through its representation in the Authority's Management Board and Audit Committee, the Commission will receive audit reports and ensures that adequate actions are defined and timely implemented by the Authority to address the issues identified. All payments will remain pre-financing payments until the Authority's accounts have been audited by the European Court of Auditors and the Authority has submitted its final accounts. If necessary, the Commission will recover unspent amounts of the instalments paid to the Authority.

The activities of the Agency will also be subject to the supervision of the Ombudsman in accordance with Article 228 of the Treaty. These administrative controls provide a number of procedural safeguards to ensure that account is taken of the interests of the stakeholders.

EFSA's Internal Control Framework is designed to provide reasonable assurance regarding the achievement of five objectives set out in Article 303 of the EFSA Financial Regulation.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The main risks relate to the Authority's performance and independence in implementing the tasks entrusted to it. Underperformance or impaired independence could hamper the achievement of the objectives of this initiative and also reflect negatively on the Commission's reputation.

The Commission and the Agency have put in place internal procedures that aim at covering the risks identified above. The internal procedures are in full compliance with the Financial Regulation and include anti-fraud measures and cost-benefit considerations. First and foremost, sufficient resources should be made available to the Authority in both financial and staffing terms to achieve the objectives of this initiative.

Furthermore, quality management will include both the integrated quality-management activities and risk-management activities within the Authority. A risk review is a continuous, proactive and systematic process, conducted annually, with risks being assessed at a residual level, i.e. taking into account controls and mitigations already in place. Conducting self-assessments (as part of the EU Agencies benchmarking programme), annual reviews of sensitive functions and ex-post controls also fall within this area, as does maintain a register of exceptions.

To preserve impartiality and objectivity in every aspect of the Authority's work, a number of policies and rules on management of competing interests have been put in place and will be regularly updated, describing specific arrangements, requirements and processes applying to the Authority's Management Board, scientific committee members and experts, the Authority's staff and candidates, as well as consultants and contractors.

EFSA's risk-based internal control and auditing scheme under the new integrated management system framework, and with the cohesive planning and reporting of respective Assurance Management activities in EFSA. The Commission will be informed timely of relevant management and independence issues encountered by the Authority and will react upon notified issues timely and adequately.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the value of the related funds managed), and assessment of the expected levels of risk of error (at payment & at closure)

The Commission's and the Agency's internal control strategies take into consideration the main cost drivers, and the efforts already taken over several years to reduce the cost of controls, without compromising the effectiveness of controls. The existing

control systems proved to be able to prevent and/or to detect errors and/or irregularities, and in case of errors or irregularities, to correct them.

In the past five years, the Commission's yearly costs of controls under indirect management represented less than 1% of the annual budget spent on subsidies paid to the Authority. The Authority allocated 5% of its total annual budget on control activities centering around integrated quality management, audit, anti-fraud measures, finance and verification processes, corporate risk management, risk assessment and self-assessment activities.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the anti-fraud strategy.

As for its activities in indirect management, the Commission shall take appropriate measures ensuring that the financial interests of the European Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportional and deterrent penalties.

To this effect, the Commission adopted an anti-fraud strategy, latest update of April 2019 (COM(2019)176), covering preventive, detective and corrective measures.

The Commission or its representatives and the European Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds. OLAF shall be authorised to carry out on-the-spot checks and inspections on economic operators concerned indirectly by such funding.

As regards the European Food Safety Authority, the anti-fraud measures are provided for in Article 25 point 9 of Regulation (EC) No 178/2002 and the framework financial Regulation (2019/715). The Management Board shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities(26) and with the legislative requirements concerning investigations conducted by the European Anti-Fraud Office.In line with the Common Approach and Article 42 of the framework financial Regulation, an anti-fraud strategy has been developed, in accordance with the European Anti-Fraud Office methodology and guidance, and is followed by the Authority.

EFSA set up and implemented measures to counter fraud and any illegal activities affecting the interests of the EFSA by putting in place a sound anti-fraud strategy and implementing rules to improve the prevention, detection and conditions for

investigating fraud, and to set out reparation and deterrence actions, with proportionate and dissuasive measures. The validity of the EFSA's Anti-Fraud Strategy is aligned with EFSA Strategy. The Authority's Anti-fraud strategy is accompanied by a corresponding action plan, outlining both specific focus areas and actions for the next years, and several continuous actions that are carried out every year, such as a specific standalone fraud risk assessment, with the identified fraud risks included in the overall Agency risk register. Mandatory anti-fraud trainings are organised as part of the awareness anti-fraud sessions. Tailored training sessions to selected Process Owners /Managers are developed in order to address the risks associated to the areas that resulted potentially more exposed to fraud . Staff are made aware of how to report any suspects of wrongdoings and disciplinary procedures are in place as per the rules of the Staff Regulations.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

Please note that an Excel tool is available on the BUDGpedia page on the Legislative Financial and Digital Statement to help you with the calculations. You are strongly advised to use it to facilitate filling in this template.

Please insert as many budget lines as needed in the two tables below.

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[70]	from EFTA countries[71]	from candidate countries and potential candidates[72]	From other third countries	other assigned revenue
2.	E.061002 European Food Safety Authority	Diff	YES	NO	NO	NO

[70] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
[71] EFTA: European Free Trade Association.
[72] Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below

3.2.1.1. Appropriations from voted budget

EUR million (to three decimal places)

HEADING 2. Competitiveness, prosperity and Security

DG: SANTE			Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
Operational appropriations										
E.061002 European Food Safety Authority	Commitments	(1a)	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172
	Payments	(2a)	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172
Appropriations of an administrative nature financed from the envelope of specific programmes										
Budget line		(3)								0,000
TOTAL appropriations	Commitments	=1a+1b+3	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172
for DG SANTE	Payments	=2a+2b+3	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172

			Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
TOTAL operational appropriations (including contribution to decentralised agency)	Commitments	(4)	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172
	Payments	(5)	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172
Ÿ TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
TOTAL appropriations under HEADING 2 of the multiannual financial framework	Commitments	=4+6	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172
	Payments	=5+6	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172

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Heading of multiannual financial framework	4	'Administrative expenditure'[7]							
DG: SANTE		Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
Ÿ Human resources		0	0	0	0	0	0	0	0
Ÿ Other administrative expenditure		0	0	0	0	0	0	0	0
TOTAL DG SANTE	Appropriations	0	0	0	0	0	0	0	0

TOTAL appropriations under HEADING 4 of the multiannual financial framework	(Total commitments = Total payments)	0	0	0	0	0	0	0	0

EUR million (to three decimal places)

		Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
TOTAL appropriations under HEADINGS 1 to 4	Commitments	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172
of the multiannual financial framework	Payments	1,166	2,379	2,426	2,475	2,525	2,575	2,626	16,172

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3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs			***Year 2028***		***Year 2029***		***Year 2030***		***Year 2031***		***Enter as many years as necessary to show the duration of the impact (see Section1.6)***						***TOTAL***	
	OUTPUTS																	
ò	***Type[8]***	***Average cost***	***No***	***Cost***	***No***	***Cost***	***No***	***Cost***	***No***	***Cost***	***No***	***Cost***	***No***	***Cost***	***No***	***Cost***	***Total No***	***Total cost***
SPECIFIC OBJECTIVE No 1[9]…																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 …																		
- Output																		
Subtotal for specific objective No 2																		
TOTALS																		

3.2.1.2. Appropriations from external assigned revenues

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	

DG: <…….>			Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
Operational appropriations							
Budget line	Commitments	(1a)					0.000
	Payments	(2a)					0.000
Budget line	Commitments	(1b)					0.000
	Payments	(2b)					0.000
Appropriations of an administrative nature financed from the envelope of specific programmes[73]							
Budget line		(3)					0.000
TOTAL appropriations for DG <…….>	Commitments	=1a+1b+3	0.000	0.000	0.000	0.000	0.000
	Payments	=2a+2b+3	0.000	0.000	0.000	0.000	0.000

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Mandatory table:

			Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
TOTAL operational appropriations	Commitments	(4)	0.000	0.000	0.000	0.000	0.000
	Payments	(5)	0.000	0.000	0.000	0.000	0.000
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	0.000	0.000	0.000
TOTAL appropriations under HEADING <….>	Commitments	=4+6	0.000	0.000	0.000	0.000	0.000

[73] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

of the multiannual financial framework	Payments	=5+6	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

Heading of multiannual financial framework	**7**	'Administrative expenditure'[74]

This section should be filled in using the 'budget data of an administrative nature' to be firstly inserted in the Annex to the Legislative Financial and Digital Statement (Annex 5[75] to the Commission Decision on the internal rules for the implementation of the Commission section of the general budget of the European Union), which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

DG: <…….>		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

DG: <…….>		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
• Human resources		0.000	0.000	0.000	0.000	**0.000**
• Other administrative expenditure		0.000	0.000	0.000	0.000	**0.000**
TOTAL DG <…….>	Appropriations	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

EUR million (to three decimal places)

74 The necessary appropriations should be determined using the annual average cost figures available on the appropriate BUDGpedia webpage.

75 If you report the use of appropriations under Heading 7, completing Annex 5 is a compulsory requirement.

		Year 2024	Year 2025	Year 2026	Year 2027	TOTAL MFF 2021-2027
TOTAL appropriations under HEADINGS 1 to 7	Commitments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
of the multiannual financial framework	Payments	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.2. Estimated output funded from operational appropriations (not to be completed for decentralised agencies)

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2024**		Year **2025**		Year **2026**		Year **2027**		Enter as many years as necessary to show the duration of the impact (see Section1.6)						**TOTAL**	
			OUTPUTS															
	Type[76]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[77]…																		
- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 …																		
- Output																		
Subtotal for specific objective No 2																		

[76] Outputs are products and services to be supplied (e.g. number of student exchanges financed, number of km of roads built, etc.).

[77] As described in Section 1.3.2. 'Specific objective(s)'

TOTALS															

3.2.3. *Summary of estimated impact on administrative appropriations*

– ☒ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☐ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below

3.2.3.1. *Appropriations from voted budget*

VOTED APPROPRIATIONS	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034
HEADING 4								
Human resources	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Other administrative expenditure	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Subtotal HEADING 4	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Outside HEADING 4								
Human resources	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Other expenditure of an administrative nature	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Subtotal outside HEADING 4	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
TOTAL	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together, if necessary, with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.4. *Estimated requirements of human resources*

– ☐ The proposal/initiative does not require the use of human resources

– ☐ The proposal/initiative requires the use of human resources, as explained below

3.2.4.1. *Financed from voted budget*

Estimate to be expressed in full-time equivalent units (FTEs)[78]

VOTED APPROPRIATIONS	Year 2024	Year 2025	Year 2026	Year 2027
• **Establishment plan posts (officials and temporary staff)**				
20 01 02 01 (Headquarters and Commission's Representation Offices)	0	0	0	0
20 01 02 03 (EU Delegations)	0	0	0	0

[78] Please specify below the table how many FTEs within the number indicated are already assigned to the management of the action and/or can be redeployed within your DG and what are your net needs.

01 01 01 01 (Indirect research)		0	0	0	0
01 01 01 11 (Direct research)		0	0	0	0
Other budget lines (specify)		0	0	0	0
• **External staff (inFTEs)**					
20 02 01 (AC, END from the 'global envelope')		0	0	0	0
20 02 03 (AC, AL, END and JPD in the EU Delegations)		0	0	0	0
Admin. Support line [XX.01.YY.YY]	- at Headquarters	0	0	0	0
	- in EU Delegations	0	0	0	0
01 01 01 02 (AC, END - Indirect research)		0	0	0	0
01 01 01 12 (AC, END - Direct research)		0	0	0	0
Other budget lines (specify) - Heading 7		0	0	0	0
Other budget lines (specify) - Outside Heading 7		0	0	0	0
TOTAL		**0**	**0**	**0**	**0**

3.2.5. *Overview of estimated impact on digital technology-related investments*

Compulsory: the best estimate of the digital technology-related investments entailed by the proposal/initiative should be included in the table below.

Exceptionally, when required for the implementation of the proposal/initiative, the appropriations under Heading 7 should be presented in the designated line.

The appropriations under Headings 1-6 should be reflected as "Policy IT expenditure on operational programmes". This expenditure refers to the operational budget to be used to re-use/ buy/ develop IT platforms/ tools directly linked to the implementation of the initiative and their associated investments (e.g. licences, studies, data storage etc). The information provided in this table should be consistent with details presented under Section 4 "Digital dimensions".

TOTAL Digital and IT appropriations	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL MFF 2021 - 2027**
HEADING 7					
IT expenditure (corporate)	0.000	0.000	0.000	0.000	**0.000**
Subtotal HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Outside HEADING 7					
Policy IT expenditure on operational programmes	0.000	0.000	0.000	0.000	**0.000**
Subtotal outside HEADING 7	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
TOTAL	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**

3.2.6. *Compatibility with the current multiannual financial framework*

The proposal/initiative:

– ☒ can be fully financed through redeployment within the relevant heading of the multiannual financial framework (MFF)

The increase of appropriations for the European Food Safety Authority in years 2028 to 2034, will be covered under Heading 2.

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

3.2.7. Third-party contributions

The proposal/initiative:

– ☒ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	Total
Specify the co-financing body					
TOTAL appropriations co-financed					

3.2.8. Estimated human resources and the use of appropriations required in a decentralised agency

Staff requirements (full-time equivalent units)

	2028	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2034**
Temporary agents (AD Grades)	11	11	11	11	11	11	11	11
Temporary agents (AST grades)	1	1	1	1	1	1	1	1
Temporary agents (AD+AST) subtotal	*12*	*12*	*12*	*12*	*12*	*12*	*12*	*12*
Contract staff	3	3	3	3	3	3	3	3
Seconded National Experts								
Contract agents and SNE subtotal	*3*	*3*	*3*	*3*	*3*	*3*	*3*	*3*
TOTAL staff	**15**	**15**	**15**	**15**	**15**	**15**	**15**	**15**

Appropriations covered by the EU budget contribution in EUR million (to three decimal places)

[Agency]: EFSA	Year **2028**	Year **2029**	Year **2030**	Year **2031**	Year **2032**	Year **2033**	Year **2034**	**TOTAL 2028 - 2034**	POST **2034**	**GRAND TOTAL**
Title 1: Staff expenditure	1,166	2,379	2,426	2,475	2,525	2,575	2,626	**16,172**	2,626	**18,799**
Title 2: Infrastructure and operating expenditure								**0,000**		**0,000**
Title 3: Operational expenditure								**0,000**		**0,000**

TOTAL of appropriations covered by the EU Budget	**1,166**	**2,379**	**2,426**	**2,475**	**2,525**	**2,575**	**2,626**	**16,172**	**2,626**	**18,799**

Overview/summary of human resources and appropriations (in EUR million) required by the proposal/initiative in a decentralised agency

[Agency]: EFSA	Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL 2028 - 2034	POST 2034	GRAND TOTAL
Temporary agents (AD+AST)	12	12	12	12	12	12	12	12	12	12
Contract agents	3	3	3	3	3	3	3	3		3
Seconded National Experts	0	0	0	0	0	0	0	0		0
Total staff	15	15	15	15	15	15	15	**15**	15	**15**
Appropriations covered by the EU Budget	1,166	2,379	2,426	2,475	2,525	2,575	2,626	**16,172**	2,626	**18,799**
Appropriations covered by fees	0,000	0,000	0,000	0,000	0,000	0,000	0,000	**0,000**	0,000	**0,000**
Appropriations co-financed (if applicable)	0,000	0,000	0,000	0,000	0,000	0,000	0,000	**0,000**	0,000	**0,000**
TOTAL appropriations	**1,166**	**2,379**	**2,426**	**2,475**	**2,525**	**2,575**	**2,626**	**16,172**	**2,626**	**18,799**

Description of tasks to be carried out by:

Temporary staff	2 AD5 • General coordination of the risk assessment process • Organisation of authors meeting • Organisation of meetings with applicants • Organisation and chairing of mtg with experts/dedicated working group • Proof reading and harmonisation of outcomes For the 9 AD6 • final risk assessment with the integration of the different lines of evidence; • specific activities to assess horizontally specific species, • drafting GD; • interface with competent authorities (mostly senior civil servants) and stakeholders in general. • Presubmission advice • Experts' consultation 1 ASTII • Administrative support to the operations
External staff	3 FGIV: • risk assessment in all areas (lower complexity tasks)

	• collect all lines of evidence, ie collect and report in a systematic manner all the info in dossiers, as well as from literature, to allow TA quick extraction and Weight of Evidence assessment; • helpdesk for IUCLID issues for biocontrol active substances

3.3. Estimated impact on revenue

– ☒ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

– ☐ on own resources

– ☐ on other revenue

– ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[79]			
		Year **2024**	Year **2025**	Year **2026**	Year **2027**
Article …….					

For assigned revenue, specify the budget expenditure line(s) affected.

N/A

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

N/A

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

The proposal does not require any additional digital tools besides the already existing ones. EFSA will use the UCLID platform when acting as rapporteur Member State. There is no specific form prescribed for the provision of technical advice to Member States- this could be subject to specific agreement between the Member States and EFSA

4.2. Data

N/A

[79] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20% for collection costs.

4.3. Digital solutions

N/A

4.4. Interoperability assessment

N/A

4.5. Measures to support digital implementation

N/A