EUROPEAN
COMMISSION

Strasbourg, 16.12.2025
COM(2025) 1030 final/2

2025/0410 (COD)

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

{SWD(2025) 1030 final}

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) No 1107/2009[2]: In line with the announcement in the Vision for Agriculture and Food, it is necessary to accelerate access to the market for new biocontrol 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 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 substances and 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 taken steps to facilitate placing on the market of biocontrol substances. For instance, updated data requirements[3],[4] and uniform principles[5] for micro-organisms were adopted in 2022 to make them more fit-for-purpose, and a Single Market Enforcement Taskforce (SMET) project[6] 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

---

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

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

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

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

contains several targeted amendments to Regulation (EC) No 1107/2009 to accelerate market access for biocontrol substances and products containing them.

Several stakeholders have submitted comments in the call for evidence of the Biotech Act[8] (14 May 2025 - 11 June 2025) asking, among other things, to streamline the regulatory process for biocontrol products and to have a clear definition for this group of substances to delineate the scope of substances benefitting from the simplification efforts proposed in the amended Regulation (EC) No 1107/2009. Their input is also included and considered in the proposed provisions.

Several Member States, in particular smaller ones, have also signalled that applicants for the authorisation of products containing biocontrol substances and 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 low-risk active substances by providing for tacit agreement in case the concerned Member State does not decide on the mutual recognition procedure in the 120-day period.

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 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 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[7] 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 [8], causing negative impacts for farmers and industry. The workshop *Zonal Authorisation Procedure – Improvements and Developments* (ZAPID) held in 2023[9] intended

[7] https://food.ec.europa.eu/plants/pesticides/refit_en

[8] 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

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

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, approvals of new active substances and first-time authorisations of plant protection products containing new active substances are often even more delayed or potential applicants find no Member State who is able to take on the role as rapporteur or reference Member State.

These delays prevent 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 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 In addition, the Commission, taking into account requests from Member States, may identify active substances with unlimited approval for which a full renewal procedure will be carried out or identify active substances with unlimited or limited approval periods for targeted reassessment. In addition, the possibility for ad-hoc reviews already foreseen in Article 21 of Regulation (EC) No 1107/2009 is maintained. 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 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 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 submit 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 the reasons for the renewal are related to protection of health or the environment but there are no immediate concerns for human health or animal 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 a further 1 year for disposal, storage and use of existing stocks, might not be sufficient for farmers to get access to suitable alternatives in cases where reasonable alternatives do not currently exist. Doubling the maximum overall length of grace periods to 3 years would allow for alternative plant protection products to be authorised in such cases, if necessary, thus preventing losses of revenue for farmers and ensuring food security for consumers.

A survey[10] 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 European Food Safety Authority (‘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 while ensuring any specific needs for further assessment of active substances are followed up.

[10] 33rd Pesticide Steering Network meeting | the Authority

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 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[11] stressed the lack of harmonisation and difficulties to make available plant protection products for minor crops, which, although occupying a lower production acreage in the Union 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[12] aims at preventing the establishment or spreading of pests that would have unacceptable economic, environmental or social impacts on Union 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

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

[12] 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).

Member States have repeatedly mentioned difficulties in this regard. Also, the Authority has indicated repeatedly in the relevant pest risk assessments that not being able to prevent such establishment 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. Most approved basic substances are biocontrol but not all. 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 on order not to create additional burden for the farmers. The clarification would not create additional burden for the seed treatment industry as treated seeds themselves are still not to be considered a plant protection product.

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[13]. Experience has shown that the current patched territorial scope under Regulation (EC) No 1107/2009 (Member State per Member State) creates barriers to 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

[13] 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)

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 Union-wide territorial scope of data protection and the same length of data protection periods for a given test or study report across the Union to increase transparency and facilitate market access for 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 provide legal certainty in procedures for applications for approval or renewal of active substances including basic substances, or for the authorisation of plant protection products that are ongoing at the time of entry into force of this Regulation and to ensure a smooth transition from the current provisions in Regulation (EC) No 1107/2009 to the amended provisions.

Regulation (EC) No 396/2005[14]: 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, but for which it is nevertheless possible to establish safe maximum residue levels in food.

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. Therefore, it 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. To advance on this, the Commission has launched in November 2025 a study to prepare an impact assessment that will consider the impacts on the EU's competitive position and the international implications and, if appropriate, the Commission will propose amendments to the applicable legal framework. In the meantime Regulation (EC) No 396/2005 should already be amended to provide that, for substances that are not approved in the Union and that have certain particularly hazardous properties, MRLs that have been set based on good agricultural practices in third countries or Codex maximum limits may be set at the limit of quantification (technical zero) if considered appropriate in the light of the outcome of an impact assessment.

Based on the scientific criteria listed in Regulation (EC) No 1107/2009[15], this includes substances with mutagenic, carcinogenic, or reprotoxic properties as well as endocrine disruptors that may cause adverse effects in humans. Therefore, no level of exposure should be allowed in order to ensure a high level of protection for consumers in the Union.

In addition, this includes substances that are persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT) substances, and very persistent and very bioaccumulative (vPvB) substances, as well as substances with endocrine disrupting properties that may cause adverse effect in non-target organisms. The adverse effects of these substances are directly

[14] 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)

[15] 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 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.

linked to their intrinsic properties. Persistent substances, by their very nature, resist degradation, resulting in prolonged presence in the environment. Their accumulation poses a significant threat to ecosystems, endangering biodiversity, agricultural production and food security. Endocrine disruptors, similarly, interfere with the hormonal systems of living organisms, causing detrimental effects not only to individual species but also to entire ecosystems. Therefore, these substances create environmental concerns of a global nature that have a connexion with the territory of the Union. Not allowing residues of these substances in food in the Union aligns with international efforts to combat pollution and supports global initiatives aimed at sustainable development and biodiversity conservation[16].

In addition, the definition of the term "import tolerance" in Article 3(2)(g) of Regulation (EC) No 396/2005 is often misunderstood. Therefore, it 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.

Article 49(2) 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 currently not applied across the board. 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 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. Therefore, the Commission proposes a more proportionate approach to allow continued marketing of products that were compliant with MRLs applicable at the time of production, even after new lower MRLs are implemented, depending on the circumstances of each specific case.

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 Union 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,

[16] Stockholm Convention on Persistent Organic Pollutants (POPs), https://www.pops.int/; Convention on Biological Diversity, https://www.cbd.int/

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[17], and planned to be completed by 14 May 2010, the review programme had to be extended a first time in 2009 until 14 May 2014[18], a second time in 2013 until 31 December 2024[19], and recently a third time until 31 December 2030[20].

The vast majority of the competent authorities in the Member States have not met the time limits for submitting the assessment reports for applications for approval of existing active substances to the European Chemicals Agency (ECHA). The main reasons for the delays, as identified in the Commission implementation report submitted to the Council and the European Parliament in June 2021[21], 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[22], which triggered the need for further data and

---

17 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)

18 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).

19 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).

20 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).

21 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

22 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).

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 sooner 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')[23], including also stakeholder representatives as observers, and agreements were reached on a number of actions[24] to accelerate the delivery of assessment reports for existing active substances. ECHA organised workshops and adopted an action plan on active substances[25]. In 2023, the Commission launched a call for expression of interest[26] by Member States to obtain financial grants to help them achieving progress in the implementation of 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 existing 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.

The approval of active substances already approved should be converted into unlimited approvals following these new rules, except for active substances identified as meeting the exclusion criteria set out in Article 5(1) of the Regulation (EU) No 528/2012 or the

---

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

[24] 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

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

[26] *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*

substitution criteria set out in Article 10, substances for which the renewal examination already started (on-going evaluation), and substances for which no application for renewal was submitted on time. In addition, the possibility is foreseen that the Commission periodically selects a number of active substances for which a renewal procedure would be triggered, while also maintaining the existing 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 Union. The requirement for publication in the EU Official Journal of the 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 decision is also disseminated on the ECHA website[27]. Therefore, it is proposed to simplify the publication of taking into account the way authorisation decisions are adopted and disseminated in other similar regulatory frameworks[28]. More concretely, the individual decisions will take the form of Commission Implementing Decisions notified only to the applicants, and summaries of those Decisions should be published in the EU Official Journal.

Regulation (EC) No 1829/2003[1]: The use of fermentation[2] processes using genetically modified micro-organisms ('GMMs') 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*[3], a *Strategy for European Life Sciences* in February 2025[4].

The European food and feed fermentation sector has voiced concerns about uncertainty of the legal status of food and feed fermentation products manufactured using GMMs, due to unclarity as regards 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 residues of 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.

However, uncertainties remain as to whether the presence of residues of the genetically modified production strain in the food or feed render the latter 'produced from a GMO' and therefore subject to Regulation (EC) No 1829/2003. In that regard, 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 aggravated the situation, raising more frequently questions on the legal framework applicable to those products, which led to different enforcement practices by national authorities, including the

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

[28] 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

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 the legal status of food and feed products manufactured using GMMs as production strains and not containing the GMM used to obtain them but potentially containing residues thereof.

In order to safeguard the smooth functioning of the internal market as regards food and feed products obtained with GMMs and to ensure legal certainty for operators, the legal status of such products is clarified by making explicit that the definition of food and feed 'produced from GMOs' does not cover food and feed products obtained using GMMs as production strains where there is no presence in those products of those GMMs and any residues thereof are limited to non-viable cells, are minimized through reasonable attempts to remove them in accordance with good manufacturing practice and have no technological effect on the food or the feed. While the specific process and the level of removal or minimization of non-viable cells that is reasonably achievable without negatively affecting the quality of the food or feed may vary depending on the production strain used, and the type of food or feed product obtained with it, the removal or minimization of non-viable cells of the GMM should be carried out in accordance with good manufacturing practices used in conventional food and feed products to minimize the presence of residues.

It should be underlined that the assessment of any risks of those food and feed products relating to the GMMs used during their production process and to any residues thereof 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[5], Regulation (EC) No 1333/2008 on food additives, Regulation (EC) No 1334/2008 on flavourings[6], Regulation (EU) 2015/2283 on novel foods[7]).

In order to be consistent with the overall applicable framework on GMOs, it should be ensured that the same rules apply to animal and plant cells, regardless of whether they are in culture, not in culture or embedded in the complete organisms. Therefore, the reference to GMMs in the definition of 'produced from GMOs' should cover only micro-organisms in the biological sense and exclude animal and plant cells in culture.

Regulation (EC) No 1831/2003: Regulation (EC) No 1831/2003 on additives for use in animal nutrition[29] was the subject of an evaluation that was published on 28 February 2024[30], 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, the Authority 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, and as a too short period to justify

[29] 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)

[30] SWD(2024) 46 final

investment costs, while resources could rather be allocated to the development of new 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.

Those findings were largely confirmed in the feedback received from business stakeholders, but also from several public authorities, in the context of the Call for Evidence published ahead of this proposal.

The proposed amendments 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, and are even strengthened, ensuring that food and feed safety standards are not compromised. The objective of the proposed simplification and clarification measures is 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 Union.

Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004: Regulation (EC) No 852/2004[31] and Regulation (EC) No 853/2004[32] 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[33]. 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) No 1099/2009[34]: As regards animal welfare at the time of killing, Member State competent authorities are currently required to submit annual reports to the Commission on depopulation operations carried out the previous year, in addition to the annual reports

[31] 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)

[32] 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)

[33] 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)

[34] 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)

submitted under the Regulation (EU) 2017/625[35]. 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. Withdrawing the obligation to submit a specific annual reports on depopulation operations, will reduce the administrative burden on Member State competent authorities and the Commission.

Regulation (EC) No 999/2001: Regulation (EC) No 999/2001[36] on transmissible spongiform encephalopathies (TSEs) was adopted in 2001 to address the bovine spongiform encephalopathy (BSE) epidemic through a strict precautionary framework. Since then, and although it is not possible to conclude that BSE is absent or has completely disappeared from the EU territory, the epidemiological situation has improved, with most Member States recognised as having negligible risk.

Moreover, the rules are misaligned with the World Organisation for Animal Health's (WOAH)standard, revised in 2023[37] and with recent scientific opinion on the BSE risk posed by ruminant collagen and gelatine derived from bones of the Authority published in 2024[38]. In this context, certain elements of the current rules should be reviewed and updated to reflect this evolution and to ensure they remain proportionate to the current level of risk for that disease in the Union.

The objective of this proposal 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 a swift 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.

---

35 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).

36 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)

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

38 https://www.efsa.europa.eu/en/efsajournal/pub/8883

Regulation (EU) 2017/625: Article 50(3) of Regulation (EU) 2017/625[39] 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.

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 stakeholders have 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 their accreditation scope. This requirement created significant challenges for reference laboratories which are expected to seek accreditation for a very large number of contaminants, pests, methods and matrices in areas such as plant health, food contact materials, feed additives and food additives, food enzymes and flavourings. The accreditation is a complex and costly process for laboratories which poses a heavy burden in terms of time and resources on reference laboratories. This problem has been repeatedly flagged by the Member States and by EU reference laboratories which 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.

Article 37(4), point (e), Article 93(3), point (a) and Article 100(2) of Regulation (EU) 2017/625 provides that official laboratories, EU reference and national reference laboratories

[39] 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)

should operate and be accredited in accordance with the EN ISO/IEC 17025 standard. Nevertheless, certain biological food safety hazards could be analysed in laboratories accredited by both the EN ISO/IEC 17025 and another similar laboratory standard such as, the 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 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 43(2), 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 proposed measures, drawing on ongoing exchanges with Member States and stakeholders, recent evaluations (in particular on the 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, the 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. Non-governmental organisation (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 plant protection products legislation, phasing down pesticide use, limiting derogations, and avoiding any reduction in oversight of active substances or authorisations. Views on aerial spraying of plant protection products 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 Union and continued prioritisation of consumer health over trade facilitation.

For biocidal products, relevant industry stakeholders and several Member States prioritised completing the review programme and simplifying renewals; most business inputs opposed the 2025 end date already set in the legislation for the protection of data submitted for existing active substances still in the review programme, referring to their concerns that other companies would benefit from free access to data, and to 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 Regulation (EU) No 528/2012.

Authorities and industry sought legal clarity on fermentation products obtained by using GMMs as a production strain to harmonise the interpretation of Regulation (EC) No 1829/2003 and its enforcement, while NGOs insisted such products should be remain covered by GMO rules, with mandatory risk assessment, traceability and labelling as genetically modified food and feed to ensure consumer choice.

Feed additives business stakeholders largely supported streamlining, unlimited in time authorisations, and wider use of digital labelling, whereas NGOs and several public authorities 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 6000 detailed position papers from stakeholders, providing additional suggestions, data and costs estimates.

- **Impact assessment**

The proposed simplification measures are highly technical in nature. There are no viable alternatives to achieve the objectives, and the proposed measures do not alter core policy objectives or introduce significant new obligations. For these reasons, a full impact assessment would not bring added value. Instead, the proposal is accompanied by an analytical staff working document. The document clearly explains the proposed measures and present the underlying evidence, analysis and stakeholders' views, as well as estimating the potential cost savings.

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 plant protection products, biocides, feed additives, would start yielding benefits quickly, while the broader plant protection products framework simplification, requiring structural changes to renewal, will have a longer transition. From 2027, business cost savings are estimated at €335,6 million annually, rising by a further €93 million per year from 2029 as plant protection products simplifications take effect. In this mandate, the ten measures are expected to deliver at least €1 billion in 2027–2029, with an additional €2.1 billion in the next mandate.

Public authorities would also gain substantially: administrative costs are projected to fall by € 661 million annually and in total, this amounts to an estimated € 4.6 billion reduction in administrative costs over 2027–2034.

- **Regulatory fitness and simplification**

This proposal is part of the commitment of the Commission to lighten the regulatory burden for people, businesses and administrations in the EU to boost prosperity and resilience of the Union 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

The proposed initiative is expected to result in an increase of EUR 15,073 million in the subsidy paid by the Commission to the Authority for the period 2028–2034. Without prejudice to the negotiations on the next MFF, the additional appropriations allocated to the agency from 2028 onwards will be compensated via redeployments from programmes under the same heading as the agency under the 2028-2034 MFF.

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) No 1107/2009**

This legislative proposal contains several targeted amendments to Regulation (EC) No 1107/2009 to accelerate market access for biocontrol substances and products containing them, including a clear definition of them under Articles 2 and 3, prioritising the approval and 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 substances for which the approval procedure is still ongoing under Article 30, and allowing the Authority 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 the Authority are proposed to take on these new tasks as indicated in the Legislative Financial Fiche. As many biocontrol substances may also have plant growth stimulation functions, a clearer borderline between biocontrol substances and biostimulants is needed to increase legal certainty for companies and a smoother enforcement by authorities.

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 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 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 is to be amended so that the approval of active substances becomes 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 regard 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 approval. A new Article 27a is inserted making the approval period of all active substances approved at the time of the entry into force of this regulation unlimited, with certain exceptions. Article 18 is amended and a new Article 18a is created to allow the Commission, taking into account requests from Member States, to identify active substances with unlimited approval for which a full renewal procedure will be carried out or identify active substances with unlimited or limited approval periods for targeted reassessment. In addition, the possibility for ad-hoc reviews already foreseen in Article 21 of Regulation (EC) No 1107/2009 is maintained. Article 32 is amended in order to maintain the limited duration for authorisations of plant protection products containing active substances with unlimited approval. Articles 43 and 44 are amended to further specify provisions related to the renewals and reviews of authorisations of plant protection products containing active substances with unlimited approval.

Article 19 is also amended to allow for the adoption of implementing rules setting out the provisions necessary for the implementation of a targeted reassessment procedure (in addition to the renewal procedure which already exists).

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

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 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 under Article 20(2) and Article 46 is increased to a maximum of one year for the sale and the distribution and an additional maximum of two years for the disposal, storage, and use of existing stocks of the plant protection products concerned, for cases where reasonable alternatives do not exist.

Article 11 is amended in order to provide the possibility for the Member States to ask for support from the Authority 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 shall be taken into account by the Member States when they assess the ‘current scientific and technical knowledge’ for the substance. However, if they consider that

an update is of that assessment is justified they shall submit a request to the Commission for harmonised assessment of the current scientific and technical knowledge concerning the active 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.

Articles 23 and 28 are amended and a new Article 23 a is inserted in order to clarify the status of the basic substances, the approval criteria 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.

Article 68 is deleted as the reports of the Member States on the official controls of plant protection products are already included in the annual reports under Article 113(1) of Regulation (EU) 2017/625.

Article 2 of the draft Regulation is introduced containing transitional provisions to provide legal certainty in procedures for applications for approval or renewal of active substances or for the authorisation of plant protection products that are ongoing at the time of entry into force of this Regulation and to ensure a smooth transition from the current provisions under Regulation (EC) No 1107/2009 to the new ones. It is clarified also that the data protection of test or study reports which started under the old rules will continue but only for the Member States where it was granted while for the rest of the Member States the new rules will apply to the same test and study report. Transitional provision on the basic substance is also included providing that all approved basic substances could be used and placed on the market notwithstanding whether they were approved also as regular active substances under the old regime where the placing on the market as a plant protection product in a Member State prevented the use of basic substance for the same use in that Member State.

- **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 for substances that are not approved in the Union and that have certain particularly hazardous properties, MRLs that were set based on good agricultural practices in third countries or Codex maximum limits may be set at the limit of quantification (technical zero) if considered appropriate in the light of the outcome of an impact assessment. .

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) and 31(1)(b) are amended accordingly to replace the abbreviation 'LOD' with 'LOQ'.

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.

- **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), Article 9 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 imposed on case-by-case basis, in the light of the outcome of the risk assessment, prior to a decision on an approval. The approval of active substances already approved will be converted into unlimited approvals following these new rules, except for active substances identified as meeting the exclusion criteria set out in Article 5(1) of Regulation (EU) No 528/2012 or the substitution criteria set out in Article 10, active substances for which the renewal examination already started for which the renewal evaluation will continue or the approval will expire when no application was submitted by the deadline (new Article 15a).

Article 13(1) is modified to specify that the renewal process is relevant for active substances with specified expiry dates of approval. In order to maintain a high level of protection of human and animal health and the environment, a new Article 14a is added so that it provides the possibility for the Commission to select a number of active substances for which a renewal procedure would be triggered. Selection criteria for active substances subject to that procedure can include, among others, relevant new or updated data requirements or guidance documents, indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data, and may take into account requests from Member States.

Articles 44 and 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.

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

Article 2, point 10, of Regulation (EC) No 1829/2003 is amended to clarify that the definition of food and feed 'produced from GMOs' does not cover food and feed products obtained with GMMs used as production strains.

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

Paragraph 8 of Article 9 is amended in order to provide that authorisations granted for feed additives are valid for an unlimited period of time, 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, which provide for mechanisms allowing a supervision and possible review of existing authorisations in order to ensure the safety of the products concerned. 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 8b 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.

Alternative measures to the option of authorisations valid for an unlimited period of time, such as longer authorisation periods for some or all feed additives or different authorisation periods according to the type of additives, were not considered as satisfactory due to a lack of objective criteria to differentiate between additives' categories or functional groups in terms of safety or efficacy or due to the risk of absence of applicants for the renewal of non-holder specific authorisations.

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 (8b).

A new Article 9a is introduced to clarify that authorisations of feed additives already granted before the entry into force of the new rules (this proposed Regulation) are deemed unlimited in time, except those concerning: (i) feed additives belonging to the category of coccidiostats and histomonostats, (ii) urgent authorisations granted under Article 15 and concerning authorisations for which no application for renewal has been submitted on time before the entry into force of the new rules (this proposed Regulation) or for which such application has been submitted but subsequently withdrawn, and (iv) authorisations for which an application for renewal has been submitted in accordance with Article 14 before the entry into force of the new rules (this proposed Regulation) and for which no decision has been taken by that date.

In addition, a new Article 14a is introduced to provide legal certainty regarding pending procedures concerning applications for renewal of authorisation that have been submitted in accordance with Article 14 as applicable before the entry into force of the new rules (this proposed Regulation) and for which no decision has been taken by that date, which must continue to be treated under the previous rules. However, it is clarified that the renewed authorisation will be valid for an unlimited period of time in accordance with the new Article 9(8).

Paragraph 1 of Article 13 concerns cases where the Authority 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, the Authority has to take into account scientific and technological developments and may request relevant information and data from the person who was the applicant for the authorisation concerned, or, where applicable, from the holder of that authorisation. In addition, considering that the the Authority's opinion is not triggered by the submission of an application for modification of an authorisation, the Authority will still have the possibility, in accordance with Articles 32 and 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 paragraph 3a 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 Community 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 Community 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. In addition, Article 2 is amended to include the definition of 'holder of the authorisation' as the natural or legal person mentioned as such in the Community Register of Feed Additives in relation to the authorisation concerned. Article 3(3) is amended as well to remove the mention of the holder of the authorisation in the Regulation granting the authorisation.

Furthermore, a new paragraph 8a is added in Article 9 to provide for the possibility to amend the Regulations granting authorisations adopted before the date of entry into force of this Regulation, and which included the name of the holder of the authorisation, with a view to including such name in the Community Register of Feed Additives instead of in those Regulations. In order to ensure uniform conditions for the implementation of Regulation (EC) No 1831/2003 regarding such amendment to Regulations granting authorisations adopted before the date of entry into force of this Regulation, implementing powers should be conferred on the Commission in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[40].

A new paragraph 4 is added in Article 13 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, avoiding the re-submission of full applications for new

[40] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

authorisations, mirroring the procedure in force for holder-specific authorisations, and will be all the more relevant under the new proposed regime of authorisations for an unlimited period of time.

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, 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.

Finally, in order to ensure uniform conditions for the implementation of Regulation (EC) No 1831/2003 regarding the modification of authorisations, implementing powers should be conferred on the Commission in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council. Furthermore, the possibility to adopt any appropriate measures in accordance with Articles 53 and 54 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[41] should continue to apply.

Paragraph 1 of Article 16 is amended to clarify the feed business operators' responsibility for the labelling particulars, in line with the provisions of Regulation (EC) No 767/2009 for the labelling of feed. Paragraph 2 also introduces 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 2.

A new paragraph 7 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 label to a 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 9 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. Those rules may relate to the nature of the information concerned, including information referred to in paragraphs 2, 4 or 5 of Article 16, and the type of digital means that may be used. However, safety-critical and essential-use information, such as that included in the authorisation, must remain on a physical label. The aim is to expand digital labelling possibilities in the future to take into account technological developments and to provide operators with greater flexibility, while preserving the core objective of ensuring safe use of feed additives. Article 21a concerning the exercise of the delegation needs to be amended in order to refer to the new empowerment granted to the Commission.

---

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

In order to take into account the expansion of the possible labelling means, Article 2(2) is amended by adding a definition for the concepts of '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[42] and Article 10 of Regulation (EC) No 853/2004[43] are amended in order to replace the specific notification procedure by the general notification procedure under Directive (EU) 2015/1535 of the European Parliament and of the Council[44], as it is simpler, and more efficient in terms of transparency, translation and time management.

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

Member State competent authorities are currently required by Regulation (EC) No 1099/2009 to submit 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) No 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 amend 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 Authority opinion.

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

[42] 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)

[43] 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)

[44] 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

knowledge, international standards and the Authority 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) 2017/625**

Article 50(3) of Regulation (EU) 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) 2017/625 are amended so that the Commission is empowered to adopt delegated acts to supplement Regulation (EU) 2017/625 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.

2025/0410 (COD)

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 to the Treaty on the Functioning of the European Union, and in particular Article 43(2), 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,

Having regard to the opinion of the European Economic and Social Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) In its Communication A Vision for Agriculture and Food[45], 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 of food and feed safety are amended by this Food and Feed Simplification 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[46] sets out the regulatory procedure for approval of active substances and authorisation of plant protection products in the Union.

(4) In order to decrease farmers' dependency on plant protection products containing chemical active substances and in line with the announcements in the Communication A Vision for Agriculture and Food, the accessibility and availability of sustainable

[45] 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

[46] 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)

plant protection products, including plant protection products containing biocontrol substances, needs to increase.

(5) In order to facilitate faster market access for biocontrol substances and products containing them, biocontrol substances need to be more clearly defined and identified under Regulation (EC) No 1107/2009. A definition for biocontrol substances should include 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, as well as substances, including of unknown and variable composition, originating from living organisms or derived by biological processes (e.g. extracts from plant products, metabolites produced by micro-organisms).

(6) As many biocontrol substances may also have plant growth stimulation functions, a clearer borderline should be set with regard to fertilising products, in particular plant biostiumlants as referred to in Regulation (EU) No 2019/1009 on the making available on the market of EU fertilising products[47]. Thus, the scope of Regulation (EC) No 1107/2009 should be clarified to exclude substances which influence positively the life processes of crops, as those substances qualify as plant biostimulants from a plant physiological perspective. Substances interfering with life processes of plants and controlling the growth of the plants or parts of them, should remain in the scope of Regulation (EC) No 1107/2009.

(7) For the same purpose, the evaluation of applications for approval of such active substances and for the authorisation of plant protection products containing them should be given priority to ensure timely crop protection from existing pests and diseases.

(8) The risk assessment of biocontrol substances requires specific technical knowledge, and some Member States do not have enough experts specialised in this type of assessment. As a result, some applicants for approval of biocontrol substances face difficulties in finding a rapporteur Member State. In order to increase capacity for the assessment of new biocontrol 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. The Authority should put in place appropriate safeguards to ensure independence of the subsequent peer review and to avoid any possible conflict of interests for the experts involved at the different stages of the assessment.

(9) To accelerate the accessibility and availability to farmers of plant protection products containing new biocontrol substances, Member States should have the possibility to grant provisional authorisations for such products 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 substance 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 set out in the approval require an amendment of the conditions set out in the provisional authorisations.

---

[47] Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003, PE/76/2018/REV/1, OJ L 170, 25.6.2019, pp. 1–114, ELI: http://data.europa.eu/eli/reg/2019/1009/oj.

(10) To reduce burdens on applicants and Member States and to facilitate the availability of plant protection products containing only biocontrol substances or low-risk active substances, the Union should be considered as one zone for applications for the authorisation of such products. Considering also that plant protection products containing only biocontrol 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.

(11) 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 substances, and to reduce the administrative burden for farmers, the obligation to keep records should not apply to plant protection products containing only biocontrol substances.

(12) 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 to that Regulation and risk-based criteria for the plant protection products containing them set out in its 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. To address such situation, he possibility to apply for a change of the status of an approved active substance to low-risk should be introduced.

(13) The provisions related to basic substances in Regulation (EC) No 1107/2009 have proven to be unclear, which has led to disharmonised implementation across Member States and hinders the availability of those substances to farmers. Therefore, a clear definition of basic substance should be included in Article 3. specifying that basic substances include foodstuff as defined under Article 2 of Regulation (EC) No 178/2002 as well as substances for which 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.

(14) Separate provisions for the approval criteria for basic substances and the application procedure should be set out, as well as more specific labelling requirements to better inform users about the conditions of use. It should also be clarified 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. Transitional provisions should be

added so that all basic substances that are approved at the moment of the entry into force of this Regulation could be placed on the market in the Union, without any restrictions stemming from the superseded rules, ensuring level-playing field for all users in all Member States.

In order to support a transition towards more sustainable active substances and plant protection products, resources in the Member States currently dedicated to renewal procedures should be made available for the assessment of applications for new active substances and products. Therefore, approvals for active substances should become unlimited in time, except for active substances that are candidates for substitution, 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 and those approved for a limited period for reasons linked to the results of the risk assessment. 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. The Commission should also be able to identify active substances with unlimited approval for which a full renewal procedure should be carried out or identify active substances with unlimited or limited approval periods for targeted reassessment. Identification of active substances should be based on multiple criteria and requests from Member States. In addition, the possibility for ad-hoc reviews of active substances at any time as already foreseen in Article 21 of Regulation (EC) No 1107/2009 should be maintained.

(15) In the interest of predictability, efficiency, consistency and transparency, rules setting out the provisions necessary for the implementation of targeted reassessments should also be created.

(16) 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 it is necessary to clarify the scope of the criteria for which such derogation is possible. A harmonised derogation in certain cases where a serious danger to plant health which cannot be contained by other reasonable means would reduce the administrative burden for Member States authorising plant protection products containing such active substances under Article 53 and will contribute to reducing disparity for access to plant protection products containing the substances concerned between the farmers located in different Member States. It should also be possible that in addition to the information included in an application for approval or renewal of approval of an active substance any other information provided in the course of the approval procedure may also be taken into account when considering the possibility to grant the derogation.

(17) 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 the Authority for support when preparing the draft assessment report for an application for approval or renewal of approval, assessing additional information required during an evaluation and updating the draft assessment report after its initial submission. The Authority should put in place appropriate safeguards to ensure independence of the subsequent peer review and to avoid any possible conflict of interests for the experts involved at the different stages of the assessment.

(18) 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 the Commission to set maximum 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 clarify that the setting of a maximum grace period for distribution and use of existing stocks of plant protection products for which authorisations have to be withdrawn is possible in general, except for cases where there are immediate and serious concerns for human or animal health or the environment and to clarify the link with Article 46. 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 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 a total period of 3 years in such cases so that it allows the Member States enough time to have alternative plant protection products authorised and to allow the farmers to adapt their crop protection solutions. For the same reasons, the grace periods in which the Member States may grant under Article 46 following withdrawals or amendments of authorisations should be aligned with the maximum possible under Article 20.

(19) The requirement for Member States to consider current scientific and technical knowledge relevant for the active substance 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. It is therefore necessary to clarify that the Member States should normally rely on in the latest active substance assessments at Union level, while also acknowledging that updates may be needed and in such cases the Member States should notify the Commission so that the scientific and technical knowledge is assessed in a harmonised way.

(20) Regulation (EU) 2016/2031[48] aims at preventing the establishment or spreading of pests that would have unacceptable economic, environmental or social impacts on the Union territory including impacts on agricultural production. The timely availability of authorised plant protection product uses is essential to apply the provisions of this Regulation. 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 prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3), 37(2) of Regulation (EU) 2016/2031 should be facilitated.

[48] 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).

(21) 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, applications 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 for authorisation of a plant protection product in certain Member States 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 the obligation to obtain the consent of the authorisation holder. Moreover, the administrative burden for such applicants, as well as for applicants for the extension of authorisations of products for minor uses, should be reduced by removing the obligation to provide, as part of the applications, certain documents which can be obtained directly from the reference Member State having granted the authorisation for which mutual recognition or extension is sought.

(22) 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 Union and their sowing. Therefore, the relevant provisions should be clarified, in order to increase harmonisation among Member States. The measures would not create additional burden for the seed treatment industry as treated seeds themselves are still not to be considered a plant protection product. The administrative burden for the farmers should be limited thus specific derogation for the machinery used for the sowing of treated seeds should be provided so that it is not to be regarded as pesticides application equipment within the meaning of Directive 2009/128/EC[49] on the sustainable use of pesticides.

(23) 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, the transparency 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.

(24) 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 to market entry for 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.

[49] 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)

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 set the same data protection period for a given study or test across the Union 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.

(25) The obligation of the Member States under Article 68 to transmit to the Commission reports on the official controls on the enforcement of Regulation (EC) No 1107/2009 has already been superseded by the obligation to transmit annual reports under Article 113(1) of Regulation (EU) 2017/625. Thus Article 68 should be deleted in order to avoid confusion and unnecessary administrative burden for the Member States.

(26) Transitional provisions are necessary in order to ensure a smooth transition for the pending approval and renewal procedures for active substances used in plant protection products, so that they are completed under the current rules but the approval period is granted under the new rules. A transitional provision is also necessary in order to ensure that a test or study report whose data protection started under the old rules does not get double protection in the same Member State under the new EU wide rules. It is further clarified that all basic substances approved at the entry into force of this Regulation could be placed on the market independent of their approval as regular active substances in order to ensure equal treatment and fair competition for all basic substances and for all farmers independent from the Member State they are based.

(27) Regulation (EC) No 396/2005[50] sets the procedure for defining maximum residue levels ("MRLs") of pesticides in or on food and feed of plant and animal origin. In the Vision for Agriculture and Food, the Commission announced it would pursue a stronger alignment of production standards applied to imported products, notably on pesticides and establish the principle, in compliance with the EU's international obligations, that the most hazardous pesticides banned in the EU for health and environmental reasons should not be allowed back to the EU through imported products. To advance on this, the Commission has launched in November 2025 a study to prepare an impact assessment that will consider the impacts on the EU's competitive position and the international implications and, if appropriate, propose amendments to the legal framework. In the meantime Regulation (EC) No 396/2005 should already be amended to provide that, for substances that are not approved in the Union and that have certain particularly hazardous properties, MRLs that have been set based on good agricultural practices in third countries or Codex maximum limits may be set at the limit of quantification (technical zero).

(28) This concerns substances with mutagenic, carcinogenic, or reprotoxic properties as well as endocrine disruptors that may cause adverse effects in humans. Therefore, no level of residues leading to exposure of consumers should be allowed in order to ensure a high level of protection for consumers in the Union.

(29) In addition, this concerns substances that are persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT) substances, and very persistent and very bioaccumulative (vPvB) substances, as well as substances with endocrine disrupting

[50] 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)

properties that may cause adverse effect in non-target organisms. Persistent substances, by their very nature, resist degradation, resulting in prolonged presence in the environment. Their accumulation poses a significant threat to ecosystems, endangering biodiversity, agricultural production and food security. Endocrine disruptors, similarly, interfere with the hormonal systems of living organisms, causing detrimental effects not only to individual species, including migratory species, but also to entire ecosystems across national boundaries. Therefore, these substances create environmental concerns of a global nature that have a connection with the territory of the Union. Not allowing residues of these substances in food in the Union aligns with international efforts to combat pollution and supports global initiatives aimed at sustainable development and biodiversity conservation[51].

(30) 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 the Authority for an evaluation under Article 43 of Regulation (EC) No 396/2005. Furthermore, the term "import tolerance" is often misunderstood. Therefore, the term "import tolerance" should be repealed and it should be clarified that the definition of good agricultural practice applies equally to the Union and to a third country for the setting of MRLs.

(31) 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.

(32) Article 16 to Regulation (EC) 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 Authority the Authority 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.

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

---

[51] Stockholm Convention on Persistent Organic Pollutants (POPs), https://www.pops.int/; Convention on Biological Diversity, https://www.cbd.int/

(34) Regulation (EU) No 528/2012[52] sets out the procedures for approval of biocidal active substances and authorisation and making available on the market and use 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 of that Regulation as those have properties that are of concern to human or animal health or the environment, and except for active substances for which time limits of approvals are considered necessary in the light of the outcome of the risk assessment conducted prior to a decision on an approval. The approval of active substances already approved should be converted into unlimited approvals following these new rules, except for active substances identified as meeting exclusion or substitution criteria under Articles 5(1) or 10 of that Regulation, active substances for which the renewal examination already started for which the renewal evaluation should continue or for which the approval should expire when no application for renewal was submitted by the deadline. A possibility should be foreseen that the Commission periodically selects a number of active substances based on specific criteria for which a renewal procedure should be triggered, while also maintaining the possibility to initiate early reviews pursuant to Article 15 of Regulation (EU) No 528/2012. Criteria for the selection of active substances subject to the renewal procedure should include, among others, relevant new or updated data requirements or guidance documents, indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data, and might take into account requests from Member States.

(35) To simplify and accelerate the procedure for adoption and publication of the decisions on 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 those Decisions should be published at the EU Official Journal for transparency.

(36) Regulation (EC) No 1829/2003 covers food and feed produced 'from' a GMO but not food and feed produced 'with' a GMO. In this regard, Recital 16 of that Regulation recalls that the Regulation does not apply to processing aids, or to food and feed which are manufactured with the help of a genetically modified processing aid. However, the scope of Regulation (EC) No 1829/2003 as regards food and feed products obtained using genetically modified micro-organisms (GMMs) as production strains is unclear given that, on the one hand, Recital 16 of that Regulation also states that the determining criterion between food and feed produced 'from' or 'with' a GMO is whether material derived from the genetically modified source material is present in the food or in the feed and, on the other hand, the definition of 'processing aid' in EU food and feed law allows, under certain conditions, for the presence in the final product of residues of the substance or its derivatives. Furthermore, the increasing sensitivity of detection methods has the consequence that food and feed that have been considered free from residues of GMMs and have been placed on the market as

[52] 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)

conventional products for many years may at some point be considered as containing such residues.

(37) Therefore, to ensure the good functioning of the internal market and provide legal certainty to food and feed business operators, food and feed products obtained using a GMM as production strain and from which the GMM has been removed should not fall within the scope of Regulation (EC) No 1829/2003 even if residues of the GMM are present in the food or feed, provided that they are limited to non-viable cells, that the presence thereof is minimized through reasonable attempts to remove them and have no technological effect on the final food or feed. In particular, in order to ensure that reasonable attempts to remove residues have been made, it should be required that they have been carried out in accordance with good manufacturing practices as those used in similar food and feed products to minimize the presence of residues.

(38) The reference to GMMs in the definition of 'produced from GMOs' should refer to GMMs as defined in Directive 2009/41/EC of the European Parliament and the Council of 6 May 2009,[53] with the exclusion of animal and plant cells in culture. In order to be consistent with the overall applicable framework on GMOs, it should be ensured that the same rules apply to animal and plant cells, regardless of whether they are in culture, not in culture or embedded in the complete organisms. The specific provisions should therefore cover only micro-organisms in the biological sense, including the taxonomic groups Archaea and Bacteria, the unicellular species and life stages of Protozoa, Chromista and Fungi, as well as filamentous fungi and viruses, while excluding animal and plant cells in culture.

(39) Regulation (EC) No 1831/2003[54] 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, in particular SMEs, but also for the Authority, the Member States and the Commission involved in the renewal procedure. In addition, the implementation of Regulation (EC) No 1831/2003 has so far led to only very few withdrawals or denials of authorisation for safety reasons, in particular on the occasion of the renewal of authorisations. 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.

(40) Alternative measures to the option of authorisations valid for an unlimited period of time, such as longer authorisation periods for some or all feed additives or different authorisation periods according to the type of additives, were not considered as satisfactory due to a lack of objective criteria to differentiate between additives' categories or functional groups in terms of safety or efficacy or due to the risk of absence of applicants for the renewal of non-holder specific authorisations.

---

53 Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance); OJ L 125, 21.5.2009, pp. 75–97

54 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).

(41) Modifications, suspensions or revocations of existing authorisations should continue to be adopted anytime where such authorisations no longer meet the safety or efficacy conditions set out in Regulation (EC) No 1831/2003, taking into account scientific and technological developments. The high safety level of protection pursued by the Regulation should continue to be ensured, considering in particular the supervision and monitoring requirements on holders of authorisations, including implementation of post-market monitoring required in authorisations granted before this Regulation, the Authority's possible scientific reassessment of authorisations on its own initiative or on Member States' or Commission's request or upon submission of applications for modification of authorisations or for the authorisation of new uses of feed additives. In view of a scientific reassessment of authorisations, the Authority's powers should include possible requests of information to applicants and authorisation-holders and the accomplishment of any relevant tasks provided by Regulation (EC) No 178/2002 of the European Parliament and of the Council[55], such as data collection, commissioning of scientific studies and use of information identified from monitoring of emerging risks. The application of these safeguards should ensure that the authorisation of feed additives for an unlimited period of time does not pose a risk to safety. Article 9 and Article 14 of Regulation (EC) No 1831/2003 should therefore be amended accordingly.

(42) In order to provide legal certainty and to ensure a smooth transition to the new rules, it should be clarified that authorisations of feed additives already granted before the entry into force of this Regulation, and which are still in force, are deemed unlimited in time, except for additives belonging to the category of coccidiostats and histomonostats, urgent authorisations granted under Article 15, authorisations for which no application for renewal has been submitted on time before the entry into force of the new rules or for which such application has been submitted but subsequently withdrawn, and authorisations for which an application for renewal of authorisation has been submitted before the entry into force of the new rules and for which no decision has been taken by that date.

(43) Applications for renewal of authorisation submitted before the date of entry into force of the present Regulation and for which no decision on that renewal has been taken yet at that date, should continue to be treated in accordance with the rules set out in Article 14 as applicable at the time of their submission. However, authorisations renewed after the entry into force of this Regulation should be valid for an unlimited period of time. Furthermore, the new rule of authorisation for an unlimited period of time should not affect the processing of existing procedures concerning applications submitted pursuant to Article 10(2) of Regulation (EC) No 1831/2003.

(44) 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 Community Register of Feed Additives, rather than be included in the terms of the Regulation granting the authorisation. In order to ensure uniform conditions for the implementation of Regulation (EC) No 1831/2003, implementing powers should be conferred on the Commission to amend

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

Regulations granting an authorisation adopted before the entry into force of this Regulation, and which include the name of the holder of the authorisation, to remove such name from those Regulations and include it in the Community Register of Feed Additives instead. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[56].

(45) 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 specifications or conditions included in that authorisation. The current absence of such procedure requires operators wishing to modify a non-holder specific authorisation to resubmit a full application for a new authorisation, which generates unnecessary burden.

(46) 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.

(47) Finally, in order to ensure uniform conditions for the implementation of Regulation (EC) No 1831/2003 regarding the modification of authorisations, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council. Articles 2, 3, 9 and 13 of Regulation (EC) No 1831/2003 should therefore be amended accordingly.

(48) 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 broader labelling means allowed in Regulation (EC) No 767/2009 of the European Parliament and of the Council[57] for feed materials and compound feed, the development of new, digital, communication means, and 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 certain non-safety related information under certain conditions of accessibility and reliability. For the purpose of ensuring the safe use of feed additives, all safety-critical and essential use information, which is in particular included in the authorisation, should however remain mandatory on the physical label. Accordingly, a distinction should be made in the context of the requirements for feed additives and premixtures between the concepts of 'labelling' and of 'label', which should be properly defined in line with the corresponding definitions laid down in Regulation (EC) No 767/2009 in order to ensure consistency. In addition, clarification should be brought concerning the labelling responsibility, in line with the provisions of Regulation (EC) No 767/2009 regarding feed labelling. Article 2 and Article 16 of Regulation (EC) No 1831/2003 should therefore be amended accordingly.

---

56 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

57 Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/767/oj).

(49) 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. Those rules may relate to the nature of the information concerned, excluding safety-critical and essential-use information, and to the type of digital means that may be used. 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. Article 21a of Regulation (EC) No 1831/2003 should therefore be amended accordingly.

(50) 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.

(51) 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 , the competent authorities of Member States are currently required to submit 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 (EU) 2017/625 on official controls and other official activities[63] The

---

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)

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)

objective of Regulation (EC) No 1099/2009 is, however, to protect animals at the time of killing. The annual compliance reports under Regulation (EU) 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 of two separate reports 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 that Regulation lacks provisions ensuring a thorough analysis and comparability of the reported information, 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.

(52) Regulation (EC) No 999/2001[64] lays down rules for the prevention, control and eradication of certain 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 and it also specifies the minimum animal subpopulations to be covered by such monitoring programme in respect of bovine spongiform encephalopathy (BSE). During its General Session in May 2023, the World Organisation for Animal Health (WOAH) 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. While 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), the updated international standards also require adaptation of the minimum bovine subpopulations covered by the monitoring programme. In order to ensure alignment with evolving scientific knowledge and international standards, Article 6 should therefore be amended so that both the age thresholds and the bovine subpopulations covered by the monitoring programme may be adapted under the procedure referred to in Article 24(3).

(53) As part of the measures aiming to prevent BSE, 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 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

---

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*

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.

(54) Article 8 of Regulation (EC) No 999/2001 provides that, after consultation of the appropriate scientific committee, the data relating to the age of bovine animals to be taken into account for determining the list of specified risk material set out in Annex V to that Regulation. In order to ensure timely alignment with evolving international standards and scientific knowledge, the list of specified risk material set out in Annex V to that Regulation should also be adapted taking into account at least the bovine spongiform encephalopathy risk categories of the country where it originates.

(55) 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 adopted in 2023 confirms, however, that gelatine and collagen derived from ruminant bones are safe commodities. This conclusion was further supported by the 2024 scientific opinion of the Authority on the BSE risk posed by ruminant collagen and gelatine derived from bones[66]. To reflect both the international standards mentioned as well as the latest scientific evidence in this regard, the provisions of Article 16 should therefore be amended to include these products, i.e. collagen and gelatine, in the scope of products not subject to restrictions for the placing on the market.

(56) In order to ensure the 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 Article 16 of Regulation (EC) No 999/2001 and 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) of that Regulation.

(57) Article 23 and 23a of Regulation (EC) No 999/2001 currently empower the Commission to amend non-essential elements of this Regulation, including by supplementing it, through 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 the timely adaptation to evolving epidemiological situations, scientific knowledge and international standards, it is appropriate to replace these empowerments with delegated acts in accordance with Article 290 of the Treaty. The Commission should therefore be empowered to amend the annexes and to supplement that Regulation. In particular, regarding 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. Regulation (EU) 2017/625[67] establishes rules on the performance of official controls by the competent

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

[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

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) 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.

(58) Regulation (EU) 2017/625 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) 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.

(59) Consignments of goods falling under the rules referred to in Article 1(2)(g) of Regulation (EU) 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.

(60) 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) 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.

(61) Regulation (EU) 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. Official laboratories are assisted by national reference laboratories designated by the Member States, and by European Union reference laboratories designated by the Commission.

(62) In accordance with point (e) of Article 37(4), point (a) of Article 93(3), and Article 100(2) of Regulation (EU) 2017/625, official laboratories, European Union reference laboratories and national reference laboratories are to operate and to be accredited in accordance with standard EN ISO/IEC 17025. However, in certain cases, such as for example the analysis for certain biological food safety hazards, sound and reliable results can be ensured by accreditation in accordance with other standards. It should

---

(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)

therefore be allowed to designate as official laboratories, European Union reference laboratories and national reference laboratories, laboratories which operate and are accredited in accordance with another standard than EN ISO/IEC 17025, provided that those laboratories comply with the conditions established by the Commission by delegated acts. Articles 41, 93 and 100 of Regulation (EU) 2017/625 should be amended accordingly.

(63) In accordance with Article 93(3), point (a) and Article 100(2) of Regulation (EU) 2017/625, the scope of the accreditation of European Union reference laboratories and national reference laboratories should include all the methods of laboratory analysis, test or diagnosis they use when operating as reference laboratories. However, accreditation is a complex and costly process, which results in a heavy 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 plant health, food contact materials, feed additives and food additives, food enzymes and flavourings poses a burden in terms of time and resources on European Union reference laboratories and national reference laboratories. In order to ensure the flexibility and proportionality of the approach without affecting the soundness and reliability of the results it should be allowed to designate as European Union reference laboratories and national reference laboratories, laboratories which are not accredited for all the methods they use for official controls and other official activities, provided that those laboratories comply with the conditions established by the Commission by delegated acts. Articles 93 and 100 of Regulation (EU) 2017/625 should be amended accordingly.

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1107/2009

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

(1) Article 2 is amended as follows:

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

‘ (b) ‘disrupting life processes of plants, such as substances regulating their growth, other than as a nutrient or a plant biostimulant’

(b) paragraph 2 is replaced by the following:

‘2. This Regulation shall apply to substances, including biocontrol 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, for uses that are solely and explicitly needed in order to prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3), 37(2) of Regulation (EU) 2016/2031 and 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) point 34 is replaced by the following:

'34. 'plant biostimulant' means a product having at least one of the following actions:

(1) stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

(a) nutrient use efficiency;

(b) quality traits;

(c) availability of confined nutrients in soil or rhizosphere;

(2) stimulating life processes of crops to improve their tolerance to abiotic stress.

Substances disrupting life processes of crops which are not fulfilling the definition of plant biostimulants are active substances covered by this Regulation.';

(c) the following point 35 is added:

'35. 'biocontrol substance' means:

(a) micro-organisms,

(b) inorganic substances as occurring in nature, with the exception of heavy metals and their salts or

(c) substances of biological origin or produced synthetically that are functionally identical and structurally similar to them.';

(d) the following point 36 is added:

'36. ´basic substances´ means active substances that are not predominantly used for plant protection purposes, including foodstuffs and substances evaluated in accordance with other Union legislation, but are nevertheless useful in plant protection.';

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

'7. By way of derogation from paragraph 1, where on the basis of documented evidence included in the application or information provided in the course of the approval procedure 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.

The derogation provided for in the first subparagraph 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, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), or that are a persistent organic pollutant (POP) according to the criteria 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 the serious danger to plant health or plant production in their territory identified pursuant to the first subparagraph.';

(4) Article 5 is replaced by the following:

'*Article 5*

First approval

The first approval shall be for an unlimited period 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 period of approval is set in accordance with Article 6 (j) in particular in the light of relevant uncertainties emerging from the risk assessment, including as a result of data gaps.';

(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 the 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. The application shall demonstrate that the active substance fulfils the approval criteria provided for in Article 4 of this Regulation or, where applicable, that the change of status of the active substance is justified. The application shall be submitted in accordance with standard data formats, where they exist pursuant to Article 39f of Regulation (EC) No 178/2002 of the European Parliament and of the Council, 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 substances may be submitted to the Authority which shall assume the duties of the rapporteur Member State.';

(6) Article 11 is amended as follows:

(a) the following paragraph 1a is added:

'1a. The rapporteur Member State shall give priority to the assessment of applications for approval of biocontrol substances.';

(b) the following subparagraph is added at the end of paragraph 2:

'The rapporteur Member State 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 substance.';

(8) the heading of Subsection 3 is replaced by the following:

'Subsection 3

Renewal, reassessment and review';

(9) Article 14 is replaced by the following:

'*Article 14*

Renewal of approval

1. Upon 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 for an unlimited period, 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 period of renewal is set in accordance with Article 6 (j) in particular in the light of relevant uncertainties emerging from the risk assessment including as a result of data gaps.';

(10) Article 18 is replaced by the following:

'*Article 18*

Work programme for renewal of approval of active substances with unlimited approval periods

1. The Commission shall periodically after consulting the Authority, adopt implementing acts in accordance with the procedure referred to in Article 79(3), identifying active substances or groups of active substances with unlimited approval periods for which a renewal procedure shall be conducted.

The identification of the active substances concerned shall take into account, among others, indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data and may take into account requests from Member States.

The Commission shall adopt an implementing act identifying all relevant active substances, as referred to in the first subparagraph, at the latest 3 years after amendments to the approval criteria set out in Annex II relevant for these active substances, or when updated data requirements or guidance documents relevant for these active substances become applicable.

2. The implementing acts referred to in paragraph 1 shall:

(a) list the active substances concerned;

(b) list the rapporteur and co-rapporteur Member States;

(c) set deadlines for the submission of applications for renewal of the approval of the active substances concerned that allow sufficient time for the generation of the necessary data and the submission of the said applications; and

(d) set expiry dates for the approvals of the active substances concerned that allow sufficient time for the submission and evaluation of the applications and for the adoption of decisions on the renewal of the approval of the active substances concerned.

3. Articles 14, 15(2), 16, 17 and 20 shall apply.';

(11) A new Article 18a is inserted:

'*Article 18a*

Work programme for targeted reassessment of active substances

1. The Commission may initiate a targeted reassessment of the approval of active substances at any time, to verify whether certain approval criteria or specific aspects thereof are, in light of current scientific and technical knowledge, still met.

It may, after consulting the Authority, and in accordance with the procedure referred to in Article 79(3), adopt implementing acts identifying active substances or groups of active substances with limited or unlimited approval periods for targeted reassessment.

The identification of the active substances concerned shall be based on the same criteria as laid down in Article 18(1).

2. The implementing acts referred to in paragraph 1 shall:

(a) list the active substances concerned;

(b) list the rapporteur and co-rapporteur Member States;

(c) set out the scope of the targeted reassessment for the active substances concerned, and indicate the specific data requirements that apply and, where relevant, the guidance documents and/or scientific opinions that shall be used; and

(d) set deadlines for the submission of the required information for the active substances concerned that allow sufficient time for the generation of the necessary data and the submission of the information.

3. Where the Commission concludes that compliance with the relevant approval criteria covered by the targeted reassessment is demonstrated, it shall adopt an implementing act, confirming the approval, where applicable with conditions and restrictions in accordance with Article 6, in accordance with the procedure referred to in Article 79(3).

4. Where the information referred to in paragraph 2 point (d) has not been provided within the time period established, the Commission shall adopt an implementing act withdrawing the approval in accordance with the procedure referred to in Article 79(3).

Where the Commission concludes that the approval criteria covered by the targeted reassessment are no longer satisfied, it shall adopt an implementing act withdrawing the approval in accordance with the procedure referred to in Article 79(3). In case the derogation set out in Article 4(7) applies, that implementing act may amend the approval.

5. Articles 13(4), 17 and 20(2) shall apply.';

(12) Article 19 is replaced by the following:

'*Article 19*

Implementing measures

An implementing act, adopted in accordance with the procedure referred to in Article 79(3), shall set out the provisions necessary for the implementation of the renewal procedure and of the targeted reassessment procedure, as provided for in this Subsection 3.';

(13) 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 may set when withdrawing or amending authorisations for plant protection products as a result of that Regulation. That maximum grace period shall normally not exceed 6 months 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 case there are no other available reasonable means to plant protection products containing the active substance concerned, the maximum grace period shall not exceed one year for the sale and distribution, and in addition a maximum of two years for the disposal, storage, and use of existing stocks of the plant protection products concerned. In case of immediate and serious concerns for human health or animal health or the environment that led to a

withdrawal or non -renewal of the approval, the Regulation referred to in paragraph 1 shall provide that the Member States may not set a grace period.';

(14) Article 22, paragraphs 1 and 2 are replaced by the following:

'1. An active substance complying with the criteria provided for in Article 4 and 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).';

(15) Article 23 is replaced by the following:

'*Article 23*

Approval criteria for basic substances

1. An approval granted pursuant to this Article and Article 23a shall cover:

(a) the direct use of the basic substance for plant protection purposes as such or when produced by the user directly from plants or parts of plants after simple preparation;

(b) the use of the basic substance in a product consisting of the basic substance and of, as applicable, a simple diluent, other basic substances or substances necessary to stabilise the product.

(c) Any product containing a basic substance with a composition not complying with point (b) of the first subparagraph shall be considered as a plant protection product and shall require an authorisation in accordance with Chapter III.

2. By way of derogation from Article 4, the basic substance shall be approved where all the following criteria are fulfilled:

(a) the basic substance 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 product in which it is approved for use;

(b) the basic substance or the product in which it is used does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects;

(c) is not an approved active substance for use in plant protection products at the time of the submission of the application for approval as basic substance and no application for an approval as an active substance is under assessment at that moment;

(d) the basic substance or the product in which it is used has neither immediate or delayed harmful effects in human health, including that of vulnerable groups, or animal health, nor unacceptable effects on the environment, arising from its use(s) for plant protection purposes.';

(16) a new Article 23a is inserted:

'*Article 23a*

Approval procedure and labelling of basic substances

1. 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) intended uses and proposed conditions of use of the basic substance;

(b) 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(s) of the substance; and

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

2. 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.

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

4. The approval shall cover all approved uses of the basic substances and any product containing it as specified under Article 23a without being limited by the uses applied for. The approval shall be for an unlimited period and Articles 59 to 62 shall not apply.

5. Where a substance approved as a basic substance is subsequently also approved as an active substance that is not a basic substance, that approval shall not affect the existing approval as a basic substance, as well as the placing on the market and use as basic substance or product as refer to in Article 23(1).

6. Any applicant may request an extension of the approved uses of a basic substance. Paragraphs 1 to 4 apply. Where justified in the light of the outcome of the evaluation, the Commission shall update the review report for the basic substance, including a reference to the applicable review report in the approval regulation.

7. 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 paragraph 2 of Article 23 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).

8. Basic substances and products referred to in Article 23(1) may be labelled as "Products containing (a) basic substance(s) for plant protection". In such case the label shall contain clear indications about their allowed use for plant protection.

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

(17) a new Article 27a is inserted:

'*Article 27a*

Approval periods of already granted approvals

1. For all active substances approved at the latest on (…) [*OP please insert the date of entry into force of this Regulation]*, approvals shall be deemed unlimited in time, except for:

(a) active substances identified as candidates for substitution in accordance with Article 24;

(b) active substances approved under Article 4(7);

(c) active substances for which the submission of an application for renewal under Article 15(1) was required before *[OP: please insert the date of entry into force of this Regulation]* but was not submitted before the deadline referred to in Article 15(1);

(d) active substances for which a procedure for the renewal of approval is ongoing on *[OP: please insert the date of entry into force of this Regulation]*.

2. The Commission shall amend the Regulation referred to in Article 78(3) in accordance with the first paragraph.';

(18) 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 basic substances or products referred to in Article 23(1).';

(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.';

(19) 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 is admissible in accordance with Article 9 and 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 into an authorisation granted in accordance with Article 36, unless the conditions set in the approval require amendment of the provisional authorisation.';

(20) Article 32 is replaced by the following:

'*Article 32*

Duration

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

Without prejudice to Article 44, the duration of an authorisation shall be set for a period:

(a) not exceeding 15 years if the plant protection product concerned contains only active substances, safeners, and synergists with unlimited approval periods, or,

(b) not exceeding 1 year from the earliest date of expiry of the approval of the active substances, safeners and synergists contained in the plant protection product concerned.

This period shall allow the examination as provided for in Article 43 to be carried out.

2. Authorisations may be granted for shorter periods to synchronise the re-evaluation of similar products for the purposes of a comparative assessment of products containing candidates for substitution as provided for in Article 50.';

(21) in Article 33, paragraph 2, point (b) is 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 prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3) and 37(2) of Regulation (EU) 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.’;

(22) 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 the application. It shall give all Member States in the same zone the opportunity to submit comments to be considered in the assessment.

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 unless it considers that an update is necessary in the light of the current scientific and technical knowledge. In this case the Member State shall request the Commission to act under Articles 18, 18a or 21.’;

(23) new paragraphs 5, 6 and 7 are added to Article 37:

‘5. 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.

6. The Member State examining the application shall give priority to the processing of applications for plant protection products containing as active substances only biocontrol substances.

7. The Member State examining an application for plant protection product uses that are solely and explicitly needed in order to prevent the entry into, and spread within, the Union, of pests listed in accordance with Articles 5(2), 30(1), 32(3) and 37(2) of Regulation (EU) 2016/2031 shall endeavour to decide as early as possible and in any case within 6 months.’;

(24) 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 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 is 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.';

(25) 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 to 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.

3. 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.

4. 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.

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

(26) Article 43 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. That application for renewal shall be submitted:

(a) No later than nine months before the expiry of an authorisation, if the plant protection product concerned contains only active substances, safeners, and synergists with unlimited approval periods, or

(b) Within 3 months from the renewal of the approval of an active substance, safener or synergist contained in the plant protection product.

(27) The applicant shall provide the following information:

(a) a copy of the authorisation of the plant protection product;

(b) any new information required as a result of amendments in data requirements or criteria;

(c) evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;

(d) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein;

(e) a report on the monitoring information, where the authorisation was subject to monitoring.';

(b) in Article 43, paragraph 5 is replaced by the following:

(28) 'Member States shall decide on the renewal of the authorisation of a plant protection product at the latest 12 months after the submission of the application;';

(29) in Article 44, a new paragraph 1a is inserted:

(30) '1a. Member States shall check compliance of all plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for in the Regulation confirming the approval under Article 18a.';

(31) 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, as a result of a Regulation adopted pursuant to Article 20(1) or as a result of a Regulation adopted pursuant to Article 21(3), Member States shall set a grace period within the limits of the maximum grace period set by the Commission on the basis of Article 20(2), unless the Commission has prohibited the setting of such a grace period on the basis of Article 20(2) .

2. Where a Member State withdraws or amends an authorisation or does not renew it for other reasons than those referred to in paragraph 1, it may set a grace period that shall not exceed 6 months 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).’;

(32) 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 a plant protection product.

2. 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.

3. Member States can only prohibit the placing on the market or the use of seeds and plant reproductive material treated with plant protection product 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.

4. In the cases referred under paragraph 3 above, the Commission may take measures to restrict or prohibit the use and/or sale of such treated seeds and plant reproductive material in accordance with the 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.

5. Articles 70 and 71 shall apply.

6. Without prejudice to other Union legislation concerning the labelling of seeds and plant reproductive material, the label and documents accompanying the treated seeds and plant reproductive material shall include the name of the plant protection product with which they were treated, its 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, where applicable, risk mitigation measures set out in the authorisation for that product.

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

(33) Article 51 is amended as follows:

(a) paragraph 2 is replaced by the following:

'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 provided for in Article 4(3)(b), (d) and (e) and Article 29(1)(i) are fulfilled;

(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, in particular data on the of residues and where necessary on the risk assessment as regards the operators, workers and bystanders.'

(b) paragraph 3 is replaced by the following:

'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.';

(c) paragraph 7 is replaced by the following:

'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 Article 41.';

(d) paragraph 9 is replaced by the following:

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

(34) 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.

2. Data protection may be granted 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 for an amendment of the 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.

3. Data protection shall be granted to the test and study reports referred to in paragraph 2 where the first applicant has requested it 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 under this Regulation has never been granted anywhere in the Union.

4. If the first applicant does not request data protection to be granted for a test or study report submitted for the first time in a dossier under this Regulation, it shall not be data protected and it could be used for the benefit of any subsequent applicants.

5. Where a test or study 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 Article 62 or in Article 80, or where:

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

(b) any period of data protection granted for the test and study reports under this Regulation has expired.

6. The period of data protection shall be 10 years starting from the date of the authorisation in the first Member State granting an authorisation based on a dossier including the test or study report. That period is extended to 13 years for plant protection products covered by Article 47.

7. The period of data protection shall be extended by three 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 extensions are made by the authorisation holder at the latest five years after the date referred to in paragraph 5.

8. The same data protection rules as for the first authorisation shall also be granted 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).

9. Data protection shall be granted to test and study reports necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months from the first renewal of the authorisation granted in accordance with Article 43 in any Member State or from the first conclusion of a review conducted in accordance with Article 44 in any Member State. The first to fifth paragraphs shall apply *mutatis mutandis*.

10. The total period of data protection may not exceed 13 years. For plant protection products covered by Article 47 the total period of data protection may not exceed 15 years.

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

(35) 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 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

Third parties such as the drinking water industry, retailers or residents may request access to this information by addressing the competent authority.

The competent authorities shall provide access to such information in accordance with applicable national or Union law'.

(36) Article 68 is deleted.

Article 2

Transitional provisions concerning Regulation (EC) No 1107/2009

(1) Article 14(2) of Regulation (EC) No 1107/2009 as amended by *[OP: please insert the reference of this Regulation]* shall, following completion of the renewal procedure, also apply to active substances for which an application for renewal of approval has been submitted before *[date of entry force of this Regulation]*.

(2) Article 59 of Regulation (EC) No 1107/2009 as it stood before being amended by this Regulation shall continue to apply to test and study reports whose data protection period in a Member State started before (…) *[OP please specify the entry into force of this Regulation*]. Article 59 of Regulation (EC) No 1107/2009 as amended by this Regulation shall apply, with the exception of Article 59(3), last sentence, to those test or study reports as of the date of their first submission for the authorisation in a plant protection product in any other Member State after (…) *[OP please specify the entry into force of this Regulation*] but shall not cover the Member States referred to in the previous sentence.

(3) Article 23a (6) of Regulation (EC) No 1107/2009 as amended by *[OP: please insert the reference of this Regulation]* shall also apply to all basic substances approved before the entry into force of this Regulation.

Article 3

Amendments to Regulation (EC) No 396/2005

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

(1) Article 3(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, either in the Union or a third country, 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. ;

(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) No 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), a new subparagraph is added:

– 'By way of derogation from point (e), where the active substance has one or more of the properties 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 or to a specific evaluation in accordance with Article 43 of Regulation (EC) No 396/2005, a MRL that has been set based on a CXL or a GAP implemented in a third country can be revoked and set in accordance with Article 18(1)(b) or Article 16 if considered appropriate in the light of the outcome of an impact assessment. ;

(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 setting or modifying MRLs provided for in Article 14 may establish transitional measures allowing for the placing or remaining on the market in the Union of products that, at the time of their placing on the market or at the time of their placing into storage after production, were compliant with the MRLs applicable or to which no MRL was applicable.

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) No 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 setting or modifying MRLs provided for in Article 18 may establish appropriate transitional measures allowing for the placing or remaining on the market in the Union of products that, at the time of their placing on the market or at the time of their placing into storage after production, were compliant with the MRLs applicable or to which no MRLs was applicable.

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*

Scientific opinion of the Authority and review of MRLs

1. 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.

2. The Commission may review maximum residue levels established under this Regulation at any time in the light of new scientific and technical knowledge, taking into account the scientific opinion referred to in paragraph 1 where appropriate. ’.

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 Article 19(1), point (b), taking into account the factors set out in Article 19(2) and (5).

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

(2) in Article 4, paragraph 3, point (h) is replaced by the following:

‘(h) the date of approval and, when appropriate, the expiry date of the approval of the active substance.’ ;

(3) in Article 9, paragraph (1), point (a) is replaced by the following:

‘(a) adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the date of approval and, when appropriate, date of expiry of the approval; or’;

(4) In Article 10, paragraph (4) is replaced by the following:

‘The approval of an active substance that is considered as a candidate for substitution and each renewal shall be for a period not exceeding seven years.’;

(5) 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 a candidate for substitution in accordance with Article 10 or a shorter period is specified in the

implementing act adopted in accordance with Article 14(4), point (a), renewing such an approval.';

(6) in Article 13, paragraph 1 is replaced by the following:

'1. Applicants wishing to seek renewal of the approval of an active substance, which is subject to a specified expiry date 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.';

(7) a new Article 14a is inserted:

'*Article 14a*

Renewal of an active substance with unlimited approval

1. The Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 82(3) identifying active substances with unlimited approval for which a renewal procedure shall be conducted. The implementing acts shall list the active substances and product-types concerned, and set the expiry date of their current approvals that allows for an evaluation of the applications and the adoption of a decision on the renewal of approval.

Article 13 and Article 14 apply *mutatis mutandis* for the submission, acceptance and evaluation of the applications.

2. The identification of the active substances concerned shall take into account, among others, relevant new or updated data requirements or guidance documents, indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge and available monitoring data, and may take into account requests from Member States.';

(8) a new Article 15a is inserted:

'*Article 15a*

Approval periods of active substances approved by *[OP, please insert the date: date of the entry into force of this Regulation]*

For all active substances approved under Regulation (EU) No 528/2012 at the latest on *[OP, please insert the date: date of the 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:

(a) active substances identified as meeting the criteria set out in Article 5(1) or Article 10;

(b) active substances for which an application for renewal was submitted by the deadline set out in Article 13(1) by *[OP, please insert the date: date of the entry into force of this Regulation]*;

(c) active substances for which no application for renewal was submitted by the deadline set out in Article 13(1) by *[OP, please insert the date: date of the entry into force of this Regulation].';*

(9) In Article 44, paragraph (5) is replaced by the following:

‘5. Upon receipt of the opinion of the Agency, the Commission shall adopt either an implementing act granting the Union authorisation of the biocidal product or an implementing act 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 the decision number, the nature of the decision, the name of the biocidal product, the active substances contained in the biocidal product, the product-types, the authorisation number, the authorisation holder, and the expiry date of the authorisation.

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).’;

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

‘Upon receipt of the opinion of the Agency, the Commission shall adopt an implementing act 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

Amendment to Regulation (EC) No 1829/2003

Regulation (EC) No 1829/2003 is amended as follows:

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

‘Food and feed which are obtained using as production strains genetically modified micro-organisms within the meaning of Art 2(b) of Directive 2009/41/EC, with the exception of animal and plant cells in culture, are not food and feed ‘produced from GMOs’ where they do not contain those micro-organisms and, if they contain residues thereof, such residues are limited to non-viable cells, their presence is minimized through reasonable attempts to remove them in accordance with good manufacturing practice and they have no technological effect on the food or the feed.’.

Article 6

Amendments 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 added:

‘(o) ‘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;

(p) ‘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 or digital means, including for advertising purposes.';

(q) 'holder of the authorisation' means the natural or legal person mentioned as such in the Community Register of Feed Additives in relation to the authorisation concerned.';

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

(3) '3. In the case of additives belonging to categories provided for under points (d) and (e) of Article 6(1) and of those additives falling within the scope of Union legislation relating to the marketing of products consisting of, containing or produced from genetically modified organisms (GMOs), no person other than the holder of the authorisation referred to in Article 9, his legal successor or successor in title, or a person acting under his written authority, shall first place the product on the market.';

(4) 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*';

_____

* Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24, ELI: http://data.europa.eu/eli/reg/2003/1830/oj).

(b) paragraph 8 is replaced by the following:

'8. Without prejudice to Article 13, the authorisation granted in accordance with the procedure laid down in this Regulation shall be valid for an unlimited period of time throughout the Union. The authorised feed additive shall be entered in the Community Register of Feed Additives referred to in Article 17 ('the Register')) upon the entry into force of the Regulation granting the authorisation. Each entry in the Register shall state the date of authorisation and shall include the particulars referred to in paragraphs 5, 6 and 7 of this Article. In addition, each entry in the Register concerning additives belonging to categories provided for under points (d) and (e) of 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 paragraphs 8a and 8b are inserted:

"8a. The Commission may, by means of implementing acts, amend the Regulations granting authorisations adopted before [OP: please insert the date = date of entry into force of this Regulation] which include the name of the respective holder of the authorisation, in order to remove such name and include it in the Register. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2).

8b. By way of derogation from paragraph 8, the authorisation granted to additives belonging to the category provided for under point (e) of 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.'.;

(5) the following new Article 9a is inserted:

'*Article 9a*

Authorisation periods of certain authorisations granted before *[OP: please insert the date = date of entry into force of this Regulation]*

Authorisations of feed additives granted before *[OP: please insert the date = date of entry into force of this Regulation]*, shall be deemed to be unlimited in time, except for:

(a) feed additives belonging to the category provided for in point (e) of Article 6(1);

(b) urgent authorisations granted under Article 15;

(c) authorisations for which no application for renewal has been submitted by the deadline set out in Article 14(1) before *[OP: please insert the date = date of entry into force of this Regulation]* or for which such application has been submitted but subsequently withdrawn;

(d) authorisations for which an application for renewalhas been submitted in accordance with Article 14 before *[OP: please insert the date = date of entry into force of this Regulation]* and for which no decision has been taken by that date.';

(6) 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 information and data relevant to the assessment. It shall forthwith transmit its 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. It shall, by means of implementing acts, take a decision on the modification, suspension or revocation of the authorisation concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2).

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 shall, by means of implementing acts, take a decision on the change concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2).

3a. Where a change concerning the holder of an existing authorisation needs to be made, the holder of that authorisation shall submit to the Commission any request for modification of the name of the holder of the authorisation, accompanied by the relevant data justifying the request. The Commission shall decide on the request for modification and shall notify the holder of the authorisation of its decision. Where the request is granted, the Commission shall adapt the relevant entry in the Register accordingly within 20 days. 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 shall, by means of implementing acts, take a decision on the modification of the authorisation concerned. Those implementing acts shall be adopted in accordance with the examination 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 the categories provided for in points (d) and (e) of 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 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, by means of implementing acts, take a decision on the modification of the authorisation concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2).

6. The Commission shall without delay inform the applicant of the decision taken in accordance with paragraphs 3, 4 and 5 as applicable. The Register shall be amended where appropriate.

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

(7) Article 14 is replaced by the following:

'Article 14

Renewal of authorisations

1. Authorisations granted under this Regulation to additives belonging to the category provided for in point (e) of Article 6(1) may be renewed 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 same time as it sends the application, the applicant shall send the following 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 since the adoption of the current authorisation, 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.

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 be automatically extended until the Commission takes a decision. Information on such extension shall be made available to the public in the Register.';

(8) the following new Article 14a is inserted:

'*Article 14a*

Rules for certain applications for renewal of authorisations submitted before [*OP: please insert the date = date of entry into force of this Regulation*]

The procedures concerning the applications for renewal of authorisations submitted in accordance with Article 14 before [*OP: please insert the date = date of entry into force of this Regulation*] and for which no decision has been taken by that date, shall be completed in accordance with Article 14 as it stood before that date. However, renewed authorisations concerned shall be valid for an unlimited period of time in accordance with Article 9(8).';

(9) Article 16 is replaced by the following:

'Article 16

Labelling and packaging of feed additives and premixtures

The person responsible for the labelling shall be the feed business operator established within the Union who first places the feed additive or the premixture of additives on the market or, where applicable, the feed business operator under whose name or business name the feed additive or the premixture of additives is placed on the market.

A feed additive or premixture of additives shall not be placed on the market unless a label is attached to its packaging or container 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 referred to in the authorisation;

(b) the name or business name and the address or registered place of business of the person responsible for the labelling referred to in this Article, and, where the producer is not the person responsible for the labelling, the name or business name and address of the producer;

(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 placing on the market, and where applicable, that of the establishment producing the additive or the premixture, pursuant to Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council[68].

(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;

(g) the batch reference number and date of manufacture.

In the case of premixtures, points (b), (d), (e) and (g) shall not apply to the incorporated feed additives.

By way of derogation from the first subparagraph, the information referred to in points (b), (d) and (g) may be provided by digital means

3. 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.

4. In addition to the information specified in paragraph 2, 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 provided for in point 1, point 2(a)(i) and 2(b)(i) of that Annex, presented in a conspicuous, clearly legible and indelible manner.

5. 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 , 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

[68] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/183/oj).

premixture as a whole. Such minimum storage life shall be determined on the basis of the minimum storage life of each of its components.

6. Additives and premixtures shall be marketed only in closed packages or closed containers which shall be closed in such a way that the fastener is damaged upon opening and cannot be re-used.

7. The information provided by digital means shall be:

(a) made available on a physical label 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 two 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.

8. 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.

9. 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. Those rules may relate in particular to the nature of the information concerned, which may include information referred to in paragraphs 2, 4 and 5, or the type of digital means that may be used. Safety-critical and essential-use information, such as that included in the authorisation, shall remain on the label attached to the packaging or container referred to in paragraph 2.';

(10) Article 21a is amended as follows:

(a) paragraphs 2 and 3 are replaced by the following:

'2. The power to adopt delegated acts referred to in Article 3(5), Article 6(3), Article 7(5), Article 16(8) and Article 21 shall be conferred on the Commission for a period of five years from 26 July 2019. The power to adopt delegated acts referred to in Article 16(9) shall be conferred on the Commission for a period of five years from *[OP: please insert the date = date of entry into force of this Regulation]*. 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.

3. The delegation of power referred to in Article 3(5), Article 6(3), Article 7(5), Article 16(8) and (9) and Article 21 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.';

(b) paragraph 6 is replaced by the following:

'6. A delegated act adopted pursuant to Article 3(5), Article 6(3), Article 7(5), Article 16(8) and (9) and Article 21 shall enter into force only if no objection has been expressed either by the European Parliament or by 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 of the Council.'.

Article 7

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 the 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. Any Member States wishing to adopt national measures referred to in paragraph 3 shall notify the Commission 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) provide any other relevant information.';

(c) paragraphs 6 and 7 are deleted.

Article 8

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 the 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. Any Member States wishing to adopt national measures referred to in paragraph 3 shall notify the Commission 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) provide any other relevant information.';

(c) paragraphs 6 and 7 are deleted.

Article 9

Amendment of Regulation (EC) No 1099/2009

In Regulation (EC) No 1099/2009 Article 18, paragraphs 4 and 6 are deleted.

Article 10

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 for the purpose of approval of the rapid tests 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 for the purpose of approval of the rapid tests . The Commission is empowered to adopt delegated acts in accordance with Article 23b amending Annex X to list those tests.';

(b) Paragraph 1a 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 amend 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 amend the list of the approved alternative tests allowing to detect BSE prior to slaughter 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 to amend the rules providing 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) in Article 23, a new paragraph 3 is inserted:

‘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 the Authority 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 Regulation.

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 11

Amendment to Regulation (EU) 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:

(a) the condition referred to in point (e) of Article 37(4) in relation to the standards in accordance with which the laboratories operate and are accredited; and

(b) the condition referred to in point (a) of Article 37(5) in relation to 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 in accordance with the standard EN ISO/IEC 17025 or with the standard defined in accordance with point (a) 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 to in Article 47(1)(c) for the purposes of performing physical checks on only part of a consignment presented at a border control post.’;

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

‘4. By way of derogation from point (a) of paragraph 3, the Commission may designate European Union reference laboratories whether or not those laboratories fulfil the conditions provided for in that point in relation to:

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

(b) the accreditation for all the methods of laboratory analysis, test and diagnosis that the laboratories use.

The Commission may designate such laboratories provided that they fulfil the conditions set out in the delegated acts adopted in accordance with paragraph 4a.

4a. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning the establishment of the conditions to be fulfilled by laboratories to be designated European Union reference laboratories in accordance with paragraph 4.';

(4) Article 100 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) the first subparagraph is replaced by the following:

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

(ii) the second subparagraph is deleted;

(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 condition 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(4a), 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(4a), 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(4a), 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 12

Entry into force and application

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

Article 13(4)(a)(ii) shall apply from [*date of entry into force of this Regulation plus 2 years*] or from the date of the entry into force of the delegated act adopted in accordance with Article 100(6) of Regulation (EU) 2017/625 in the area of protective measures against pests of plants, whichever is the earliest.

This Regulation shall be binding in its entirety and directly applicable in all Member States

Done at Strasbourg,

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

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE 3
1.1. Title of the proposal/initiative 3
1.2. Policy area(s) concerned 3
1.3. Objective(s) 3
1.3.1. General objective(s) 3
1.3.2. Specific objective(s) 3
1.3.3. Expected result(s) and impact 3
1.3.4. Indicators of performance 3
1.4. The proposal/initiative relates to: 4
1.5. Grounds for the proposal/initiative 4
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 4
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. 4
1.5.3. Lessons learned from similar experiences in the past 4
1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments 5
1.5.5. Assessment of the different available financing options, including scope for redeployment 5
1.6. Duration of the proposal/initiative and of its financial impact 6
1.7. Method(s) of budget implementation planned 6
2. MANAGEMENT MEASURES 8
2.1. Monitoring and reporting rules 8
2.2. Management and control system(s) 8
2.2.1. Justification of the budget implementation method(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed 8
2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them 8
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) 8
2.3. Measures to prevent fraud and irregularities 9
3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE 10
3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected 10

3.2. Estimated financial impact of the proposal on appropriations 12
3.2.1. Summary of estimated impact on operational appropriations 12
3.2.1.1. Appropriations from voted budget 12
3.2.1.2. Appropriations from external assigned revenues 17
3.2.2. Estimated output funded from operational appropriations 22
3.2.3. Summary of estimated impact on administrative appropriations 24
3.2.3.1. Appropriations from voted budget 24
3.2.3.2. Appropriations from external assigned revenues 24
3.2.3.3. Total appropriations 24
3.2.4. Estimated requirements of human resources 25
3.2.4.1. Financed from voted budget 25
3.2.4.2. Financed from external assigned revenues 26
3.2.4.3. Total requirements of human resources 26
3.2.5. Overview of estimated impact on digital technology-related investments 28
3.2.6. Compatibility with the current multiannual financial framework 28
3.2.7. Third-party contributions 28
3.3. Estimated impact on revenue 29
4. DIGITAL DIMENSIONS 29
4.1. Requirements of digital relevance 30
4.2. Data 30
4.3. Digital solutions 31
4.4. Interoperability assessment 31
4.5. Measures to support digital implementation 32

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 (the Authority).

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 the Authority 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 the Authority 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[69]

☒ 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 protection 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.

Expected generated EU added value (ex-post) The involvement of the Authority 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.

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

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 Simplification 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 the Authority to conduct the new tasks will be covered by an increase in the Authority 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[70]

☒ **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.

---

[70] 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 (the Authority) 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. The Authority's Internal Control Framework is designed to provide reasonable assurance regarding the achievement of five objectives set out in Article 303 of the Authority 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.

The Authority'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 the Authority. 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.

the Authority set up and implemented measures to counter fraud and any illegal activities affecting the interests of the Authority 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 Authority's Anti-Fraud Strategy is aligned with the Authority 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

- 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.[71]	from EFTA countries [72]	from candidate countries and potential candidates [73]	From other third countries	other assigned revenue
2.	E.061002 European Food Safety Authority	Diff	YES	NO	NO	NO

[71] Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
[72] EFTA: European Free Trade Association.
[73] 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

HEADING 2. Competitiveness, prosperity and Security

EUR million (to three decimal places)

DG: SANTE			Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
Operational appropriations										
06 10 02 European Food Safety Authority	Commitments	(1a)	1,087	2,217	2,261	2,307	2,353	2,400	2,448	**15,073**
	Payments	(2a)	1,087	2,217	2,261	2,307	2,353	2,400	2,448	**15,073**
Appropriations of an administrative nature financed from the envelope of specific programmes										
Budget line		(3)								**0,000**
TOTAL appropriations for DG SANTE	Commitments	=1a+1b+3	**1,087**	**2,217**	**2,261**	**2,307**	**2,353**	**2,400**	**2,448**	**15,073**
	Payments	=2a+2b+3	**1,087**	**2,217**	**2,261**	**2,307**	**2,353**	**2,400**	**2,448**	**15,073**

Figures in the tables above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

EUR million (to three decimal places)

				Year	Year	Year	Year	Year	Year	Year	TOTAL MFF 2028-2034
				2028	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	
• TOTAL operational appropriations (all operational headings)	Commitments	(4)		1,087	2,217	2,261	2,307	2,353	2,400	2,448	**15,073**
	Payments	(5)		1,087	2,217	2,261	2,307	2,353	2,400	2,448	**15,073**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)		0,000	0,000	0,000	0,000	0,000	0,000	0,000	**0,000**
TOTAL appropriations Under Heading 1 to3	Commitments	=4+6		**1,087**	**2,217**	**2,261**	**2,307**	**2,353**	**2,400**	**2,448**	**15,073**
of the multiannual financial framework (Reference amount)	Payments	=5+6		**1,087**	**2,217**	**2,261**	**2,307**	**2,353**	**2,400**	**2,448**	**15,073**

Figures in the tables above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

EUR million (to three decimal places)

.

[Agency]: EFSA	**Year**	**Year**	**Year**	Year	Year	Year	Year	**TOTAL 2028 - 2034**	POST	**GRAND TOTAL**
	2028	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**		**2034 (Annual expenditure)**	
Budget line: EFSA/ EU Budget contribution to the agency	1,087	2,217	2,261	2,307	2,353	2,400	2,448	15,073	2,448	17,521

Figures in the tables above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

==========

Heading of multiannual financial framework	4	‘Administrative expenditure’[1]

EUR million (to three decimal places)

DG:SANTE		Year 2028	Year 2029	Year 2030	Year 2031	Year 2032	Year 2033	Year 2034	TOTAL MFF 2028-2034
Ÿ Human resources		0,000	0,000	0,000	0,000	0,000	0,000	0,000	**0,000**
Ÿ Other administrative expenditure		0,000	0,000	0,000	0,000	0,000	0,000	0,000	**0,000**
TOTAL DG SANTE	Appropriations	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**

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)

TOTAL HEADING 1 to 4 C1

		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	**1,087**	**2,217**	**2,261**	**2,307**	**2,353**	**2,400**	**2,448**	**15,073**

of the multiannual financial framework	Payments	**1,087**	**2,217**	**2,261**	**2,307**	**2,353**	**2,400**	**2,448**	**15,073**

Figures in the tables above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

==========

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**		**TOTAL 2028-2034**		**POST**		**GRAND**	
⇩			**2028-2034**				**2034**		**TOTAL**	
	OUTPUTS									
	Type	Average cost	No	Cost	No	Cost	No	Cost	No	Cost
SPECIFIC OBJECTIVE No 1…										
- Output										
- Output										
- Output										
Subtotal for specific objective No 1										
SPECIFIC OBJECTIVE No 2 ...										
- Output										
- Output										
- Output										
Subtotal for specific objective No 2										
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**

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)[74]

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
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

[74] 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.

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)

– ☐ 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)	9	9	9	9	9	9	9	9
Temporary agents (AST grades)	1	1	1	1	1	1	1	1
Temporary agents (AD+AST) subtotal	*10*	*10*	*10*	*10*	*10*	*10*	*10*	*10*
Contract staff	5	5	5	5	5	5	5	3
Seconded National Experts								
Contract agents and SNE subtotal	*5*	*5*	*5*	*5*	*5*	*5*	*5*	*5*
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(annual expenditure)**	**GRAND TOTAL**
Title 1: Staff expenditure	1,087	2,217	2,261	2,307	2,353	2,400	2,448	**15,073**	2,448	**17,521**
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	**1,087**	**2,217**	**2,261**	**2,307**	**2,353**	**2,400**	**2,448**	**15,073**	**2,448**	**17,521**

Figures in the tables above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

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(annual expenditure)**	**GRAND TOTAL**
Temporary agents (AD+AST)	10	10	10	10	10	10	10	**10**	10	**10,000**
Contract agents	**5**	**5**	**5**	**5**	**5**	**5**	**5**	**5**	5	**5,000**
Seconded National Experts	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**		**0,000**
Total staff	15	15	15	15	15	15	15	**15**	15	**15,000**
Appropriations covered by the EU Budget	1,087	2,217	2,261	2,307	2,353	2,400	2,448	**15,073**	2,448	**17,521**
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	**1,087**	**2,217**	**2,261**	**2,307**	**2,353**	**2,400**	**2,448**	**15,073**	**2,448**	**17,521**

For the year 2028, staff expenditure has been estimated at 50% of the projected amount, as it is anticipated that not all positions will be filled from the beginning of the year.

Figures in the tables above are all strictly indicative pending the outcome of the 2028-2034 MFF negotiations which cannot be prejudged.

Description of tasks to be carried out by:

Temporary staff	1 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 8 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	5 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[75]			
		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. the Authority 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 the Authority

4.2. Data

N/A

[75] 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