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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	11412/26
Subject:	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 - Presidency compromise text

Delegations will find in the Annex a Presidency compromise text in relation to the above proposal.

Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strikethrough~~.

The latest changes compared to the previous version (ST 11412/26) are highlighted in green.

ANNEX

PUBLIC

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[1], 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[2] 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 plant protection products, including plant protection products containing biocontrol substances, needs to increase. **In addition, to foster innovation, the access to the market of plant protection products containing only active substances which have not been approved in the Union at [date of entry into force of this Regulation] should also be facilitated, even if the active substance is not a biocontrol active substance.**

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

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

(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**: 1)** micro-organisms, **2)** inorganic substances as occurring in nature~~, with the exception of heavy metals and their salts,~~ **3) substances of biological origin or produced synthetically that are functionally and structurally identical to them, or 4)** ~~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~~**biostimulants** as referred to in Regulation (EU) No 2019/1009 on the making available on the market of EU fertilising products[3]. Thus, the scope of Regulation (EC) No 1107/2009 should be clarified to ~~exclude~~**include only** substances ~~which influence positively the life processes of crops, as those substances qualify as plant biostimulants from a plant physiological perspective. Substances interfering with~~**regulating the** life processes of plants**, such as phytohormones or other substances that mimic, inhibit or otherwise modulate endogenous hormonal signalling pathways, thereby producing specific, predictable, and dose dependent physiological or developmental responses influencing plant or plant organs'** ~~and controlling the~~ growth **and/or development. Products stimulating life processes of crops whose effect in the plant are directly related to better nutrition intake or a nutritional function or stimulating life processes of crops, other than plant nutrition processes, to improve their tolerance to abiotic stress** ~~of the plants or parts of them,~~ should remain ~~in~~**outside** the scope of Regulation (EC) No 1107/2009.

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[3] 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.

(7) For the same purpose, the evaluation of applications for approval of ~~such~~ **biocontrol** active substances and for the authorisation of plant protection products containing ~~them~~ **only low-risk active substances** 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.

(8a) To facilitate the uniform application of these measures, the Commission should mandate the Authority to develop a guidance document clarifying the concept of 'functional identicality and structural similarity' applying to the substances fulfilling the definition of biocontrol substances.

(9) To accelerate the accessibility and availability to farmers of plant protection products containing new ~~biocontrol~~**low-risk active** substances, Member States should have the possibility to grant provisional authorisations for such products as soon as the **Authority has launched the public consultation on the** draft assessment report **delivered by the rapporteur Member State** for an application for approval ~~has been delivered~~ concluding that the substance can be approved **meeting the criteria set out in Annex II point 5 of ~~this~~ Regulation (EC) No 1107/2009**. When the new ~~biocontrol~~ **low-risk active** 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. **As regards plant protection products containing as active substances only biocontrol substances, those that can benefit from the provisional authorisation are those which meet the low-risk criteria set out in Annex II, point 5, of ~~this~~ Regulation (EC) No 1107/2009.**

(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 **not yet approved in the Union at [OP: please insert the date of entry into force of this Regulation] and which are not candidates for substitution**, **the applicant should have the possibility to submit the application for the authorisation of a plant protection product containing only such active substances to a single Member State to be evaluated for all zones of the Union. Alternatively, the applicant may also choose to submit an application to one Member State to evaluate the plant protection product for the zone of that Member State** ~~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.~~

PUBLIC

(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 **to identify low-risk active substances** should therefore be ~~simplified to only refer to~~**limited 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 generated later showed that these are fulfilled. To address such situation, the 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.

PUBLIC

(14a) 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 **low-risk active substances and authorisations for plant protection products containing as active substances only low-risk** 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 **to verify if existing criteria are still met or if new criteria are fulfilled**. **Targeted reassessments should be conducted through a dedicated work programme. This work programme should be communicated transparently with clear planning and timelines, so that competent authorities of Member States can plan accordingly.**

(15a) **Following the targeted reassessment of an active substance, safener or synergist, existing plant protection products containing those substances should also be reassessed to check whether they comply with the conditions of approval for the active substance, safener or synergist contained therein, and with the requirements for authorisation of plant protection products set out in Article 29 of Regulation (EC) No 1107/2009. Applicants should provide the necessary information to demonstrate such compliance and Member States should assess it.**

PUBLIC

(15b) **Additionally, to reduce the administrative burden both for economic operators and national authorities, longer periods for the first approval and subsequent renewals of approval of active substances, other than low-risk active substances, should be set out. The approval periods for active substances approved as candidates for substitution or under the derogation in accordance with Article 4(7) of Regulation (EC) No 1107/2009 however remain unchanged. To maintain a high level of protection of human health and the environment, current legislation already gives the Commission ~~should have~~ the possibility to ask the Authority to review relevant scientific literature and monitoring data, when available, on approved active substances.**

(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 **or plant production** which cannot be contained by other reasonable ~~means~~**alternatives** 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 **relevant** information provided **by the applicant upon request of the Commission, the Authority or the rapporteur Member State, or submitted by one or more Member States** 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[4] 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.

(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.

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[4] 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).

(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~~ **by extending the current rules to plant reproductive materials other than** 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~~[5]**and clarifying the conditions under which such products could be placed** on the ~~sustainable use of pesticides~~**Union market**.

(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.

~~5~~ ~~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)~~

(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. 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. **Furthermore, to reduce the administrative burden, the changes introduced by this Regulation as regards the unlimited approval or the extension of the approval periods should also apply to active substances already approved on [date of entry into force of this Regulation].**

PUBLIC

(27) Regulation (EC) No 396/2005[6] 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. **On this basis the Commission may** ~~and~~, if appropriate, propose amendments to the legal framework**, including to Article 14 of Regulation (EC) No 396/2005**. In the meantime **the procedure for setting out MRLs in** 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, ~~**have negative effects on honeybees or accumulate in unacceptable levels in groundwater,**~~ MRLs that have been set based on good agricultural practices in third countries or Codex maximum limits ~~may~~**should** be **reconsidered and** set at the limit of quantification (technical zero**), if considered appropriate based on a prior impact assessment**. **The decision on setting or lowering MRLs should be based** ~~**take into account, in addition to**~~ **on the risk assessment of the Authority and on compliance with international obligations, in particular the General Agreement on Tariffs and Trade 1994, and the Sanitary and Phytosanitary Measures Agreement, and the Convention on Biological Diversity, and take into account an assessment of the impact on the food and feed chain in the Union.** ~~**Member States, in compliance with international obligations, in particular the General Agreement on Tariffs and Trade 1994 and the Sanitary and Phytosanitary Measures Agreement**~~t.

~~(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~~

[6] 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).

~~residues leading to exposure of consumers should be allowed in order to ensure a high level of protection for consumers in the Union.~~

PUBLIC

(29) ~~In addition,~~ This concerns **substances with mutagenic, carcinogenic or reprotoxic properties as well as endocrine disruptors that may cause adverse effects in humans and** substances that are persistent organic pollutants (POP), persistent, bioaccumulative and toxic (PBT) substances, and very persistent and very bioaccumulative (vPvB) substances, as well as substances with endocrine disrupting properties that may cause adverse effect in non-target organisms. Persistent substances, by their very nature, resist degradation, resulting in prolonged presence in the environment. Their 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 **may** create environmental concerns of a global nature that have a connection with the territory of the Union. ~~Not allowing residues of these~~ **In addition, this concerns active** ~~substances in food in the Union aligns with international efforts to combat pollution and supports~~**which have unacceptable effects on honeybees or on the survival or development of their colonies, given the growing worldwide concern that the decline of pollinators is a serious threat to** ~~global initiatives aimed at~~ **biodiversity, the environment and** ~~sustainable development, as well as to maintaining agricultural productivity and food security. Furthermore, it concerns active substance for which normal conditions of use would lead to a concentration of the active substance or of metabolites, degradation or reaction products in groundwater at a level not complying with the approval criteria for active substances. Groundwater is a valuable but limited natural resource and its and biodiversity conservation~~[7] **is equally a global concern. For coherence reasons and not to undermine the efforts already undertaken in the Union to ensure a high level of protection of human health and the environment, it is important to have a stringent approach towards their residues in imported products, in compliance with international obligations.**

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

(29a) **For residues of such active substances, the Commission should systematically assess existing MRLs set out in accordance with Codex Alimentarium (CLX) or GAP in a third country. Based on the outcome of a prior impact assessment, the Commission, should, as appropriate, lower them or set new MRLs.**

(29b) **To allow for the continued and effective use of plant protection products under the derogation set out in Article 4(7) of Regulation (EC) No 1107/2009, MRLs related to uses relying on such a derogation should remain in place despite the properties of the active substance.**

(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, **to simplify Regulation (EC) No 396/2005,** the term "import tolerance" **which refers to an MRL based on good agricultural practices (GAP) in a third country** should **no longer be used**~~be repealed~~ and it should be clarified that ~~the definition of good agricultural practice applies equally to~~**an MRL can be based either on a GAP in** the Union ~~and to~~**or on a GAP in** a third country ~~for the setting of MRLs~~.

(31) **In additions,** 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. **Such transitional arrangements should equally apply to products under storage in a third country for the purpose of sale on the Union market, including offering for sale or any other form of transfer, to ensure equal treatment between imported and domestic products.**

(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.

PUBLIC

(34) Regulation (EU) No 528/2012[8] 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~~**a longer** duration **of 15 years** for the **first** approval of active substances **and 25 years for the subsequent renewals**, except for active substances meeting exclusion or substitution criteria under Articles 5(1) or ~~10~~**10(1)** 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 **shorter** 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 **also** be converted into ~~unlimited~~ approvals ~~following these new rules~~**of 15 years**, **for those active substances for which the approval has not been renewed at least once, and, respectively, 25 years for those active substances which have already been renewed,** except for active substances identified as meeting exclusion or substitution criteria under Articles 5(1) or ~~10~~**10(1)** 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 **as well as** requests from Member States.~~

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8 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)

(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~~**residual GMM material** and have been placed on the market as conventional products for many years may at some point be considered as containing such ~~residues~~**residual GMM material**. **This situation has raised practical questions concerning, inter alia, how to ensure compliance with Regulation (EC) No 1829/2003.**

(37) Therefore, to ensure the ~~good~~**effective** functioning of the internal market and provide legal certainty to food and feed business operators, food and feed products ~~obtained using~~**produced with the assistance of** 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~~**residual GMM material is** present in the food or feed, provided that ~~they are limited to~~**it is** non-viable ~~cells~~, that the presence thereof is minimized through reasonable attempts to remove ~~them and have~~**it and it has** no technological effect on the final food or feed**. Where no removal steps have been applied to avoid the presence of non-viable residual GMM material, the food or feed should**

fall within the scope of Regulation (EC) No 1829/2003. In particular, in order to ensure that reasonable attempts ~~to remove residues~~ have been made **to remove residual GMM material**, 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~~**residual GMM material**. **To that end, the Commission, in cooperation with the Member States, should develop guidance on such practices, taking into account the nature of the product and the production process, to assist operators and authorities in determining whether these conditions are met. The absence of viable residual GMM material can be demonstrated by suitable culture-based methods, as described in the Guidance of the Authority on the characterisation of microorganisms in support of the risk assessment of products used in the food chain.**

PUBLIC

(37a) The presence of any residual GMM material in the food or the feed should not present a safety risk to human or animal health or the environment and, therefore, fulfil the general food and feed safety requirements in accordance with Regulation (EC) No 178/2002. The risk assessment concerning any such residual GMM material is carried out under the relevant food and feed legislation for the specific product, such as Regulation (EC) No 1831/2003 of the European Parliament and of the Council[9], Regulation (EC) No 1333/2008 of the European Parliament and of the Council[10] and Regulation (EU) 2015/2283 of the European Parliament and of the Council[11].

(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,[12] 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.

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9 **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.**

10 **Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008, p. 16.**

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

12 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.

(39) Regulation (EC) No 1831/2003[13] sets out the grounds and procedures for authorisation of feed additives in the Union. **In order to simplify the existing legal framework, it should be clarified that**~~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~~**does not apply to** feed additives **and feed containing them which are intended for export to third countries. However, such a derogation** should be ~~granted for an unlimited period of time, except for additives belonging~~**applicable only subject to specific conditions concerning those products including in particular certain labelling and packaging requirements, to ensure traceability and to facilitate the correct application and enforcement of the Regulation. In addition, such derogation is without prejudice** 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~~**application of relevant Union law to the products concerned, such as other Union law on animal feed and the provisions of Regulation (EC) No 178/2002, as appropriate**.

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[13] 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).

(39a) **Regulation (EC) No 1831/2003 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.

PUBLIC

(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[14], 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.

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[14] 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).

(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~~**Union** Register of Feed Additives, rather than be included in the terms of the Regulation granting the authorisation**. To avoid unnecessary administrative burden and since safety reasons do not require the immediate adaptation of all existing stocks of the products concerned, feed additives produced and labelled before such a change in the Register should be allowed to be placed on the market afterwards**. 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 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~~**Union** 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[15].

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15 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).

(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~~**European Union** 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.

PUBLIC

(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 **concept of** labelling ~~means allowed~~**as defined** in Regulation (EC) No 767/2009 of the European Parliament and of the Council[16] 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~~**by a reference to** 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.

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16 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~~**or amending that** 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**. In addition, in order to facilitate controls while ensuring the effective functioning of the internal market and to take into account technical progress, 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 the establishment of acceptable tolerances for the labelled compositional values of additives or premixtures**. 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[17]. 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.

(49a) In order to ensure consistency with more recent Union law concerning placing on the market and use of feed, certain definitions laid down in Regulation (EC) No 1831/2003 should be replaced by a reference to definitions provided for in Regulation (EC) No 767/2009.

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17 OJ L 123, 12.5.2016.

(50) Regulation (EC) No 852/2004[18] sets the hygiene requirements for foodstuffs while Regulation (EC) No 853/2004[19] 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 **methods of** 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[20]. 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.

PUBLIC

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18 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)

19 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)

20 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)

(51) Regulation (EC) No 1099/2009[21] 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[OBJ][22] The ~~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 **also** 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.

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21 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)

22 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)

(52) Regulation (EC) No 999/2001[23] 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[24] 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 international standards as regards the commodities harbouring the greatest BSE infectivity based on the BSE risk ~~category~~**status** of the country where such commodities are originating.

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[23] 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

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

(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~~**BSE risk status** 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 **European Food Safety** Authority on the BSE risk posed by ruminant collagen and gelatine derived from bones[25]. To reflect both the international standards mentioned as well as the latest scientific evidence in this regard, **only** 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.

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[25] the Authority BIOHAZ Panel, Scientific Opinion on the potential BSE risk posed by the 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

(57) Article 23 and 23a of Regulation (EC) No 999/2001 currently **provide that the Annexes to that** ~~empower the Commission to amend non-essential elements of this~~ Regulation **may be amended or supplemented, and that certain technical measures may be adopted**~~,~~ ~~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~~**the power to amend the Annexes should be** delegated ~~acts~~**to the Commission** in accordance with Article 290 of the Treaty. The ~~Commission~~**regulatory procedure with scrutiny** 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[26] 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.~~**continue to apply only to the specific technical measures listed in** 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~~**23a**.

~~[26] 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)~~

(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~~**commodity** covered by the same phytosanitary certificate may be subjected to physical checks of various types and durations. In some cases, certain ~~items~~**commodities** could be released immediately while others need to be detained pending the results of laboratory analysis**. In the event of testing different commodities, the time required for official laboratories to deliver results may vary depending on the plant pests relevant to these commodities**. 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 **and control points on consignments of plants, plant products and other objects entering the Union** 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)~~**Articles 50(3) and 53(2)** of Regulation (EU) 2017/625 should be amended to allow the competent authorities of the border control posts **and control points** 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.

(60a) **Furthermore, Regulation (EU) 2017/625 should be amended to allow the use of CHED for wood packaging material as referred to in Article 43(1) of Regulation (EU) 2016/2031 and for consignments of plants as referred to in the lists established pursuant to Article 73 of Regulation (EU) 2016/2031, to maintain the existing practice and avoid unnecessary administrative burden stemming from the mandatory application of the Notification of Arrival, as set out in Delegated Regulation (EU) 2024/2104.**

(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 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~~**to** 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~~**regulating** 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.;'

(aa) point 27 is replaced by the following:

'27. 'greenhouse' means a walk-in, static, closed place of crop production with a usually translucent outer shell, and which effectively restricts the release of plant protection products into the environment. Open tunnel structures are not considered greenhouses.;

For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (for example, for production of mushrooms or witloof) are also considered as greenhouses;';

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(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**, other than plant nutrition processes,** to improve their tolerance to abiotic stress.

~~Substances~~ **Products** ~~disrupting~~**regulating** life processes **other than in the ways referred to in points 1 and 2** ~~of crops which are not fulfilling the definition of plant biostimulants~~**, but rather by mimicking, inhibiting, or otherwise interfering with endogenous plant hormonal signalling pathways** are ~~active substances~~ **plant protection products** 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 **and structurally** identical ~~and structurally similar~~ to them~~.~~**, or**;

(ca) 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) Article 4 is amended as follows:

(a) **the first subparagraph of paragraph 1 is replaced by the following:**

'1. An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge including risk management measures and application techniques, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.'

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

'3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, including risk management measures and application techniques, shall meet the following requirements:'

(c) paragraph 7 is replaced by the following:

'7. By way of derogation from paragraph 1, where on the basis of documented evidence **(i)** included in the application **for approval or renewal of approval** or**, (ii)** ~~information~~ provided **upon request of the Commission, the Authority or the rapporteur Member State by the applicant** in the course of the approval **or renewal** procedure **or, (iii) submitted by one or more Member States in the course of the approval or renewal 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 evidence referred to in the first subparagraph shall be submitted during the approval or renewal of approval process, by the applicant or the Member States and, where relevant, supported by official or scientific bodies involved in agricultural activities.

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.;

At the same time, Member States may draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods.'

PUBLIC

(4) Article 5 is replaced by the following:

‘Article 5

First approval

The first approval shall be for ~~an unlimited~~ **a** period **not exceeding 15 years,** except for~~:~~ **low-risk active substances for which the period shall be unlimited.**

~~(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) **of** 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.

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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) **in paragraph 2,** 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;'

PUBLIC

(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~~ **shall be for a period not exceeding 25 years, except for** active substances **renewed as low-risk active substances for which the period** shall be ~~for an~~ unlimited ~~period, except for:~~**.**

~~**A shorter period may be established in accordance with Article 6(j).**~~

The renewal of approval of active substances covered by Article 4(7) shall be for a period not exceeding 5 years.

~~(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.;’~~

PUBLIC

(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

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~~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)~~**take into account one or more of the following: information notified by authorisation holders according to Article 56, any other indications of safety concerns for human or animal health or the environment, new scientific or technical knowledge, available monitoring data, or requests from Member States**.

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**, or the Authority if applicable**;

(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

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(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

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

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(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~~ **alternatives** 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.;’

~~**(13a) In Article 21, paragraph 1, before the first subparagraph, the following subparagraph is added:**~~

~~**‘The Commission may mandate the Authority to review relevant scientific literature and, if available, monitoring data on the safety of approved active substances. The Authority shall report its findings to the Commission and the Member States for consideration.’**~~**;**

PUBLIC

(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. **Such products shall not contain any co-formulants listed in Annex III;**

(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;

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(b) the basic substance ~~or~~ **and** the product in which it is used does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects **and is not carcinogenic, mutagenic or toxic for reproduction**;

(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 **and there is no need for setting maximum residue levels**, 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.

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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~~ **23(1)**. 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~~**referred** 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).

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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**, but not go beyond,** clear **and comprehensive** indications about their allowed use for plant protection **and the approval conditions and restrictions**. **In case the basic substance or product referred to in Article 23(1) is placed on the market specifically for plant protection purposes, the labelling is mandatory and uses outside of plant protection do not need to be mentioned on the packaging.**

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 **active substances** already granted approvals **approved on [OJ please insert the date of entry into force of this Regulation]**~~

~~1. For all**low-risk** active substances approved at the latest on (…) [OP please insert the date 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) **low-risk** 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) **low-risk** 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.~~

~~2a. For active substances not covered by paragraph 1 which are approved on [OP: please insert the date of entry into force of this Regulation] and for which no renewal procedure is ongoing on that date, the approval shall be deemed to be extended by the following periods:~~

~~(a) by 5 years for active substances the approval of which has not been renewed at least once under Article 14;~~

~~(b) by 10 years for active substances the approval of which has been renewed at least once under Article 14.~~

~~The Commission shall amend the Regulation referred to in Article 78(3) to extend their approval period.~~

~~2b. Paragraph 2a shall not apply for:~~

~~(a) active substances identified as candidates for substitution;~~

~~(b) active substances that are approved under Article 4(7);~~

~~(c) active substances for which a reduced period of approval is set in accordance with Article 6 (j);~~

~~(d) actives substances for which a review of approval in accordance with Article 21 is ongoing on the date referred to in paragraph 2a. If the outcome of the review confirms that the approval criteria are still satisfied, the Commission shall amend the Regulation referred to in Article 78(3) to extend their approval for the periods referred to in paragraph 2a;~~

~~e) active substances classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogen category 2, mutagen category 2 or toxic for reproduction category 2.~~'

(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~~ **points are** 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.;

(fa) the introduction and use of a plant protection product for the purpose of the treatment of seeds or other plant reproductive material in the professional treatment facilities of that Member State, provided that such plant protection product is authorised for such use in at least one Member State and is not placed on the market or used for any other purpose in the Member State of introduction.

(fb) the introduction and use of a plant protection product for the purpose of the treatment of seeds or other plant reproductive material in professional treatment facilities of that Member State for the purpose of exporting them outside the Union, provided that such plant protection product is authorised for such use in a third country and contains only active substances approved in the European Union.'

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(19) Article 30 is replaced by the following:

‘Article 30

Provisional authorisations for plant protection products containing ~~biocontrol~~**low-risk** active substances

1. By way of derogation from Article ~~29(1)(a)~~**29(1), point (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~~ **as active substances only** active substances **expected to meet the criteria set out in Annex II, point 5, to this Regulation** 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) **and the criteria set out in Annex II point 5 to this Regulation**;

   (aa) the Authority has launched a public consultation thereupon;

   (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)~~**29(1), points (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).

PUBLIC

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~~:~~ **not exceeding 1 year from the date of expiry of the approval of the active substances, safeners and synergists contained in the plant protection product and thereafter for as long as the active substances, safeners and synergists contained in the plant protection product are approved.**

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

Without prejudice to Article 44, authorisations shall be valid for an unlimited time if the plant protection product concerned contains as active substances only low-risk active substances with unlimited approval periods, and does not contain safeners or synergists, and the plant protection product has been assessed according to this Regulation considering the latest assessments underlying the approvals of the concerned low-risk active substances, contained in the product.

PUBLIC

~~(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 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.

In the case of an application for a plant protection product containing only active substances not yet approved in the Union at [*OP: please insert the date of entry into force of this Regulation*] provided that they are not candidates for substitution, the applicant may propose only one Member State to evaluate the application taking account of all zones. In this case, the applicant shall submit a complete dossier covering all zones. The applicant shall also send the summary or complete dossier as referred to in Article 8 to other Member States on request. ;'

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(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~~ **approved or endorsed** 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~~**in Article 37, the following** paragraphs ~~5, 6 and 7~~ are added ~~to Article 37~~:

‘5. ~~**For the purpose of paragraphs 4, Member States may provide that for** Where the application concerns a plant protection product containing as active substances only biocontrol or low-risk active substances **the authorisation shall be deemed to have been granted if the competent authorities** and the Member States concerned have not adopted a decision after 120 **after 120** days, the authorisation shall be deemed as having been granted by the Member States. **In that case, the Member States concerned shall issue the authorisation, send it to the applicant and inform of the publication of this information on the authorised plant protection product in accordance with Article 57(1), in particular the authorisation number. In case Member States do not opt for tacit authorisation, they shall inform the Commission thereof without delay.**~~

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~~ **low-risk active** 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~~ **low-risk** active substances**, or where the authorisation was granted following an application submitted in accordance with the second subparagraph of Article 33, paragraph 2, point (b), for plant protection products containing only active substances that have not been approved in the Union at [*OP: please insert the date of entry into force of this***

***Regulation*], provided that they are not candidates for substitution,** 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**, as well as evidence that the product has already been placed on the market in 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. ~~**Member States may provide that, for plant protection products containing as active substances only low-risk active substances, the authorisation shall be deemed as having been granted if the competent authority** 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 authorisation shall be deemed as having been granted by the Member State. **In that case the Member State shall issue the authorisation, send it** to **the applicant and inform of the publication of this information on the authorised plant protection product in accordance with Article 57(1), in particular the authorisation number. In case Member States do not opt for tacit authorisation, they shall inform the Commission thereof without delay.**~~

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.'~~

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~~(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.';~~

(30a) The heading of Subsection 4 is replaced by the following:

'Subsection 4

Renewal, reassessment, withdrawal and amendment'

PUBLIC

(30b) The following Article 43a is inserted:

'Article 43a

Targeted reassessment of authorisation

1. Following confirmation of the approval of an active substance, safener or synergist in accordance with Article 18a, an authorisation for a plant protection product containing such substance(s) shall undergo targeted reassessment upon application to verify whether the authorisation still meets the requirements of Article 29.

2. Within 3 months from the confirmation of the approval of a substance in accordance with Article 18a, the authorisation holder shall submit the application and the following information to allow for a targeted re-assessment of the authorisation:

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

(b) any new information required as a result of the amendments in data requirements or criteria assessed under Article 18a;

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

(d) a report on the monitoring information, where the authorisation was subject to monitoring.

3. Member States shall check compliance of the plant protection products containing the active substance, safener or synergist concerned with any conditions and restrictions provided for in the confirmation of the approval in accordance with Article 18a.

The Member State referred to in Article 35 within each zone shall coordinate the compliance check and assessment of the information submitted for all Member States within that zone.

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4. Member States shall decide on the confirmation of the authorisation of a plant protection product at the latest 12 months after the confirmation of the approval of the active substance, safener and synergist contained therein in accordance with Article 18a.

5. Where the information referred to in paragraph 2 of this Article has not been provided within 3 months of the confirmation of the approval of an active substance, safener or synergist in accordance with Article 18a, the Member State shall withdraw the authorisation. Article 46 shall apply.'

(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).;'

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(32) Article 49 is replaced by the following:

‘Article 49

Placing on the market of treated seeds ~~and~~ **or other** plant reproductive material

1. The treatment of seeds ~~and~~ **or other** plant reproductive material with plant protection products ~~as well as the sowing of the treated seeds and plant reproductive material constitutes~~ **is** a use of a plant protection product.

2. Placing on the market and use of seeds ~~and~~ **or other** plant reproductive material treated with a plant protection product which is not authorised in any Member State is prohibited.

2a. Member States may allow seeds or other plant reproductive material treated with plant protection products whose authorisation has been withdrawn or amended after the time of treatment to be used for sowing or planting provided that such seeds and plant reproductive material comply with the requirements of Union legislation on plant reproductive material, unless specific provisions regarding such continued use have been laid down in the withdrawal or amendment of the authorisation.

3. Member States can only prohibit the placing on the market or the use of seeds ~~and~~ **or other** 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.

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6. Without prejudice to other Union legislation concerning the labelling of seeds **or other** ~~and~~ plant reproductive material, the label and documents accompanying the treated seeds **or other** ~~and~~ plant reproductive material shall include the name of the plant protection product with which they were treated, **the year of treatment**, 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~~ **hazard statements and precautionary statements** as provided for in Regulation (EC) No 1272/2008 **and the implementing act adopted under Article 65(1)** and, where applicable, risk mitigation measures set out in the authorisation for that product.

6a. Detailed rules for the implementation of Article 49 may be established in accordance with the procedure referred to in Article 79(3).

~~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)~~**, points (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 **magnitude** 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).;’

(33a) In Article 53, paragraph 1, a third subparagraph is inserted:

‘In its assessment, another Member State from the same zone may consider using ~~grant the same emergency authorisation based on~~ that detailed information before deciding whether to grant an authorisation in accordance with this Article.‘

(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.

6a. The Commission shall set up and maintain an EU database enabling the registration and verification of the protected tests and study reports submitted under this Regulation. The database shall be publicly accessible.

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6b. Member States shall enter the relevant information concerning the protected tests and study reports into the database referred to in paragraph 6a within three months from the date on which the relevant decision becomes final.

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**, reassessment** 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~~**Articles 43 and 43a**~~ in any Member State, **or from the first confirmation of the authorisation granted in accordance with Article 43a 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 **1 to 5 of this Article** 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).;'

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(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.

(36a) The following Article is inserted:

‘Article 81a

Transitional provisions concerning Regulation [OP: please insert the reference of this Regulation]

1. Article 14(2) 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 is ongoing on [OP: please insert date of entry force of this Regulation].

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2. **Article 59 as it stood before being amended by Regulation [OP: please insert the reference of this Regulation] shall continue to apply to test and study reports whose data protection period in a Member State started before [OP please insert the date of the entry into force of this Regulation]. Article 59 as amended by Regulation [OP: please insert the reference of 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 insert the date of the entry into force of this Regulation] but shall not cover the Member States referred to in the previous sentence.**

3. **Article 23a (5) as amended by [OP: please insert the reference of this Regulation] shall also apply to all basic substances approved before [OP: please insert the date of entry into force of this Regulation].'**

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

(a) low-risk 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);

(b) low-risk 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].

The Commission shall amend the Regulation referred to in Article 78(3) in accordance with the first sub-paragraph.

5. **For active substances not covered by paragraph 4 which are approved on [OP: please insert the date of entry into force of this Regulation] and for which no renewal procedure is ongoing on that date, the approval shall be deemed to be extended by the following periods:**

(a) by 5 years for active substances the approval of which has not been renewed at least once under Article 14;

(b) by 10 years for active substances the approval of which has been renewed at least once under Article 14.

The Commission shall amend the Regulation referred to in Article 78(3) in accordance with the first sub-paragraph.

6. Paragraph 5 shall not apply for:

(a) active substances identified as candidates for substitution;

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

(c) active substances for which a reduced period of approval is set in accordance with Article 6 (j);

(d) actives substances for which a review of approval in accordance with Article 21 is ongoing on the date referred to in paragraph 5~~2a~~. If the outcome of the review confirms that the approval criteria are still satisfied, the Commission shall amend the Regulation referred to in Article 78(3) to extend their approval for the periods referred to in paragraph 5.'

~~*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.~~

PUBLIC

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 paragraph **(2a) is inserted**~~is added~~:

‘**2a.** By way of derogation from **paragraph 2,** 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**,** ~~**or does not meet criteria 3.8.3 or 3.10 of that Annex,**~~ according to the latest available evaluation under Regulation (EC) No 1107/2009 or to a specific evaluation in accordance with Article 43 of **this** 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~~ **shall be reconsidered and** set in accordance with Article 18(1)(b) or Article 16 ~~if considered appropriate in the light of the outcome of an~~ **of this Regulation and based on a prior** impact assessment**. The decision on setting an MRL shall be based on the risk assessment of the Authority and compliance with international obligations, taking into account an assessment of the impacts on the food and feed chain in the Union.**

By derogation from the duration foreseen in Article 14(1), the Commission shall submit to the Committee referred to in Article 45(1) the results of the impact assessment and, where appropriate, the draft Regulation, without delay and ~~**at the latest**~~ **within six months after:**

(i) an evaluation under Article 43 of this Regulation ~~establishes that the substance meets one or more of the properties referred to in the first subparagraph~~; or

(ii) the expiry of the maximum grace period established at the adoption of a Regulation under Regulation (EC) No 1107/2009 non-approving, non-renewing or withdrawing the approval of an active substance meeting one or more of the properties or criteria referred to in the first subparagraph.

This paragraph shall not apply to MRLs for products on which uses of plant protection products containing the active substance are authorised in the Union in accordance with the derogation set out in Article 4(7) of Regulation (EC) No 1107/2009.';

(b) A new paragraph **2b** is inserted:

'**2b**. 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, **including storage in a third country for the purpose of sale in the Union,** 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.

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(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.;’

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(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. .'

PUBLIC

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 **granted for 15 years** ~~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~~ **a shorter** 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 **granted for 25 years** ~~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.;~~'

PUBLIC

(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]

1. 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~~ **as granted for 15 years from the date of approval for substances approved but for which the approval has not yet been renewed at least once, or the expiry date of approval shall be extended by 10 years for active substances whose approval has already been renewed at least once** ~~for the concerned product-types~~, except for:

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

(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].

2. The Commission shall, by means of implementing acts, extend the expiry date of approvals for the concerned active substances for the concerned product-types only for the first time in accordance with paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).’;

(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)..’

PUBLIC

Article 5

Amendment to Regulation (EC) No 1829/2003

In Regulation (EC) No 1829/2003**, Article 2, point (10), is replaced by the following** ~~is amended as follows~~:

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

''10. 'produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs; food and feed which are ~~obtained using as production strains~~**produced with the assistance of** genetically modified micro-organisms ~~within the meaning of Art 2(b)~~**as defined in Article 2, point (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..~~**:**

(a) they do not contain such genetically modified micro-organisms; and,

(b) if they contain residual material of such genetically modified micro-organisms, such residual material meets all the following conditions:

(i) it is non-viable;

(ii) its presence is minimized through reasonable attempts to remove it in accordance with good manufacturing practice; and

(iii) it has 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) The word 'Community' shall be replaced by the word 'Union' in the entire Regulation.

(-1a) The words 'Community reference laboratory' shall be replaced by the words 'European Union reference laboratory' in the entire Regulation.

(-1b) In Article 1, paragraph 2, the following point (c) is added:

'(c) feed additives, premixtures and other feed containing them, which are intended for export to third countries, provided that they comply with the following conditions:

(i) the feed additives shall not consist of antibiotics, other than coccidiostats or histomonostats;

(ii) the feed additives, premixtures and other feed containing them shall be kept in closed packages or closed containers which shall be closed in such a way that the fastener is damaged on opening and cannot be re-used;

(iii) the packaging or container shall bear a label indicating in a conspicuous, clearly legible and indelible manner, in at least the national language or languages of the Member States in which the feed additives, premixtures and other feed containing them are located until export:

- **the mention "only for EXPORT – not for feeding animals in the EU";**
- **the designation of the feed additive, including the name of the active substances contained therein;**
- **the name or business name and the address or registered place of business of the establishment producing and processing the additives, premixtures and other feed containing them;**

PUBLIC

- **where applicable, the approval number of the establishment producing and processing the additives, premixtures and other feed containing them, pursuant to Article 10 of Regulation (EC) No 183/2005 of the European Parliament and of the Council [(*)];**

- **the batch reference number and date of manufacture.'**

(1) ~~in~~ Article 2~~, paragraph 2, the following points are added~~ **is amended as follows**:

(a) paragraph 1 is replaced by the following:

'For the purposes of this Regulation, the following definitions apply:

(a) the definitions of 'feed', 'feedingstuff', 'feed business', 'feed business operator', 'placing on the market' and 'traceability' laid down in Regulation (EC) No 178/2002;

(b) the definitions of 'label', 'labelling', 'feed materials', 'compound feed', 'complete feed', 'complementary feed', 'food-producing animal', 'non-food producing animals' and 'pet' laid down in Regulation (EC) No 767/2009.'

(b) paragraph 2 is amended as follows:

(i) points (b), (c), (d) and (g) are deleted;

(ii) the following point is 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;~~

PUBLIC

~~(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~~**Union** 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~~**successors** in title, or a person acting under his written authority, shall first place the product on the market.';

(3) In Article 7(3), point (e), the term 'complementary feedingstuffs' is replaced by the term 'complementary feed';

(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*';

PUBLIC

* 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~~**Union** 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 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 of entry into force of this Regulation]

Authorisations of feed additives granted before [OP: please insert the 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~~**the submission of an** application for renewal ~~has been submitted by the deadline set out in~~ **under** Article 14(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 14(1)** or for which such application has been submitted but subsequently withdrawn;

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

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(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 **and shall forthwith transmit such information and data received to the Member States and to the Commission**. 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).

PUBLIC

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 **inform the Member States and shall** adapt the relevant entry in the Register accordingly within 20 days. **The Register shall keep track of the successive holders of the authorisation and of the dates of change. The feed additive concerned, which has been produced and labelled before the date of the change of holder of authorisation indicated in the Register in accordance with the rules applicable before that date, may continue to be placed on the market and used until stocks are exhausted.**

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).

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5. Where, taking account of scientific and technological developments, the Commission, the ~~Community~~ **European Union** 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~~ **European Union** 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 **or, where applicable, the holder of the authorisation,** of the decision taken in accordance with paragraphs **2,** 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 ~~= 12 months after the~~ ~~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 ~~= 12 months after the~~ ~~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~~**, in the version in force on [OP: please insert the date of entry into force of this Regulation minus one day]**. 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

1. 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.

2. 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 **or, in case of feed additives referred to in Article 6(1), point (e), the category** 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;

(ba) 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 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[1] ~~.~~**;**

(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.~~ **;**

(ga) the date of manufacture.

In the case of premixtures, points (b), **(ba),** (d), (e)**, (g) and (ga)** ~~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)~~**(ba)**, (d) and ~~(g)~~**(ga)** 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 **or, where provided for in Annex III, the written medium accompanying it,** 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 premixture as a whole. Such minimum storage life shall be determined on the basis of the minimum storage life of each of its components.

PUBLIC

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~~**document** to the competent authority upon request **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**;

   (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.

8a. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to supplement this Regulation by establishing permitted tolerances for discrepancies between the labelled compositional values of feed additives or premixtures and the values analysed in official controls in compliance with Regulation (EU) 2017/625 of the European Parliament and of the Council.

PUBLIC

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.;~~

9a. The Commission is empowered to adopt delegated acts in accordance with Article 21a in order to amend this Regulation by establishing the information which may be provided in a digital format, which may include information referred to in paragraphs 2, 4 and 5 and in Annex III. 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.

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[1] 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).'

PUBLIC

(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)~~**16 (8a), (9) and (9a)** 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~~**[OP: please insert the date = 5 years from the date of entry into force of this Regulation]**. 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)**, (8a), (9) and (9a)** ~~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)**, (8a), (9) and (9a)** ~~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..’

(10a) In Annex IV, point 3, the term ‘supplementary feedingstuffs’ is replaced by the term ‘complementary feed’ and the term ‘complete feedingstuffs’ is replaced by the term ‘complete feed’.

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.

PUBLIC

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.

PUBLIC

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~~**999/2001** 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~~ **amending the list of approved** rapid tests ~~and to amend the list set out~~ **provided for** 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 **the list of approved rapid tests provided for in** 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~~ **Annex** according to scientific progress and after consultation of the European Food Safety Authority.;'

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

PUBLIC

(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 **the** 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. **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.**;’

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(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) **in paragraph 1,** 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~~**by laying down detailed rules for the placing on the market of products of animal origin referred to in** paragraphs 1 to 6 **of this Article**;’

(5) ~~in~~ Article 23~~, a new paragraph 3 is inserted~~ **is replaced by the following**:

‘Article 23

Amendment of the Annexes and transitional measures

1. The measures referred to in Article 23a shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 24(3).

~~3~~**2**. ~~Without prejudice to paragraphs 1 and 2,~~ The Commission is empowered to adopt delegated acts in accordance with Article 23b ~~amending~~ **to amend** the Annexes **of this Regulation and lay down any appropriate transitional measures**. 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 **opinion of the European Food Safety**~~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 **on the Commission** 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 **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 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~~.;'

(1a) in Article 45, the following paragraph is added:

'5. For wood packaging material as referred to in Article 43(1) of Regulation (EU) No 2016/2031 and for consignments of plants as referred to in the lists established pursuant to Article 73 of Regulation (EU) No 2016/2031, the competent authorities may request operators responsible for the consignment to complete the relevant part of the Common Health Entry Document (CHED), providing the information necessary for the immediate and complete identification of the consignment and its destination. In such a case, Article 50(1) to (3), Article 56(3) to (5) and Article 57 shall apply mutatis mutandis and Article 4(3) of Delegated Regulation (EU) 2024/2104 shall not apply.

The first subparagraph shall not apply to goods entering the Union through a border control post of first arrival located in a Member State that does not opt for requesting a CHED.'

(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~~**. However,** in the case of consignments of ~~goods~~ **plants, plant products and other objects** referred to in Article ~~47(1)(c) for the purposes of performing~~ **47(1), points (c), (e) and (f), competent authorities may request a split if the** physical checks on ~~only part of a~~ **parts of the** consignment ~~presented at a border control post~~ **require more time than those on the remaining part, allowing for the release of that remaining part for which official controls have been completed**.;'

(2a) in Article 53, paragraph 2 is replaced by the following:

'2. Article 50(3), point (b) of Article 56(3), point (a) of Article 57(2), Article 59(1), points (a) and (d) of Article 60(1) and Articles 62 and 63 shall also apply to the control points referred to in point (a) of paragraph 1 of this Article.;'

(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.;

By [OP: please insert the date = 18 months from the date of entry into force of this Regulation] the Commission shall adopt a delegated act in accordance with the first subparagraph, concerning the designation of reference laboratories in the area of protective measures against pests of plants.;'

(4a) In Article 113(2), the following subparagraph is inserted after the first subparagraph:

PUBLIC

‘The standard model forms shall specify the information and data (including quantitative data) to be submitted in relation to the relevant legal provisions, ensuring a high level of informative value and comparability at Union level.’

(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.;’

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(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 **by** 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.

However,

~~**(a) Articles 1 and 6 shall apply from [OP: please insert the date =12 months after the date of entry into force of this Regulation];**~~

(b) Article ~~13(4)(a)~~**11, point (4)(a)**(ii) shall apply from [**OP: please insert the date =** 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*

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