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NOTE

From:	General Secretariat of the Council
To:	Delegations
No. prev. doc.:	8433/26
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 the fourth Presidency compromise text in relation to the above proposal, limited to veterinary and food related issues ('cluster C', Articles 5-12 and recitals 1-2 and 36-63).

Additions to the Commission proposal are indicated in **bold**, deletions are marked as ~~strikethrough~~. Changes compared to the third compromise text are indicated in **bold underlined** or ~~strikethrough underlined.~~

Based on the discussions in the previous AGS meeting and the comments received in writing, the Presidency is proposing the following main changes:

- In recital 39 wording is added with regard to the newly introduced point (c) in Article 1(2) of Regulation (EC) No 1831/2003 that clarifies that this Regulation should not apply to feed

additives, premixtures and other feed containing them intended for export to third countries subject to specific requirements set out in the new point (c);

- In recital 44 a sentence is added reflecting the addition, in Article 13(3a), of the provision that feed additives produced and labelled before the date of a change in the Register concerning the holder of an existing authorisation should be allowed to be placed on the market afterwards without relabelling;
- In recital 54 the term "BSE risk categories" is replaced by "BSE status" to ensure consistent terminology with recital 53;
- Article 6, amending Regulation 1831/2003:
  - the newly introduced point (c) in Article 1(2) is extended to other feed containing feed additives or premixtures covered by this point, to ensure that also feed containing non-authorised feed additives or premixtures will not be fed to animals in the EU and can be properly controlled until export from the EU;
  - point (c)(iii) is reworded to avoid creating a list of steps that could be interpreted as exhaustive and to clarify that the conditions apply to non-authorised additives etc., wherever they are located in the Union until export;
  - in the first bullet point of (c)(iii) the wording is adjusted to clarify the intention to prohibit such additives etc. to be fed to animals in the EU (the new wording avoids the notion of 'use' which may also cover the further processing of an additive in a premixture for example).

In Article 11, amending Regulation 2017/625, changes suggested to Articles 56 and 57 are included for further consideration given the support by a large number of delegations.

PUBLIC

ANNEX

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

PUBLIC

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.

[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) 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.

[…]

N.B. Recitals 3-35 related to Regulations (EC) No 396/2005, (EC) No 1107/2009, (EU) No 528/2012 ('cluster B') are addressed separately

(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~~ **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~~ **residual GMM material is** ~~are~~ present in the food or feed, provided that **it is** ~~they are limited to~~ non-viable ~~cells~~, that the presence thereof is minimized through reasonable ~~reasonably achievable~~ attempts to remove **it** ~~them~~ and **it has** ~~they have~~ 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 ~~reasonably achievable~~ attempts **have been made** to remove ~~residues~~ **residual GMM material** ~~have been made~~, it should be required that they have been carried out in accordance with good manufacturing practices as those used in similar food and feed products to minimize the presence of ~~residues~~ **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 ~~residues~~ 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.

(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[2], Regulation (EC) No 1333/2008 of the European Parliament and of the Council[3] and Regulation (EU) 2015/2283 of the European Parliament and of the Council[4].

(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,[5] with the exclusion of animal and plant cells in culture. In order to be consistent with the overall applicable framework on GMOs, it should be ensured that the same rules apply to animal and plant cells, regardless of whether they are in culture, not in culture or embedded in the complete organisms. The specific provisions should therefore cover only micro-organisms in the biological sense, including the taxonomic groups Archaea and Bacteria, the unicellular species and life stages of Protozoa, Chromista and Fungi, as well as filamentous fungi and viruses, while excluding animal and plant cells in culture.

(39) Regulation (EC) No 1831/2003[6] sets out the grounds and procedures for authorisation of feed additives in the Union. **To simplify the existing legal framework, Regulation (EC) No 1831/2003 should not apply to feed additives, premixtures and other feed containing them intended for export to third countries. However, such a derogation should be applicable only subject to specific requirements concerning the feed additives, as well as the labelling and the packaging of the feed additives, the premixture or the other feed containign them, to facilitate the correct application and enforcement of the Regulation.**

(39a) ~~It~~ **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

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2 **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.**

3 **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.**

4 **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.**

5 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

6 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).

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.

(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[7], 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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[7] 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, feed additives produced and labelled before such a change in the Register should be allowed to be placed on the market afterwards without relabelling.** 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[8].

(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.

(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

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[8] 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).

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

(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 **or amending** ~~the~~**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. 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[10]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. Article 21a of Regulation (EC) No 1831/2003 should therefore be amended accordingly.

(50) Regulation (EC) No 852/2004[11] sets the hygiene requirements for foodstuffs while Regulation (EC) No 853/2004[12] lays down specific hygiene rules for food of animal origin. Regulations

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9 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).

10 OJ L 123, 12.5.2016.

11 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)

12 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)

(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[13]. The existence of two notifications procedures has proved to be cumbersome and confusing. It would be more efficient to simplify the notification requirements for national measures and to bring them in line with the more general provisions of that Directive. Regulations (EC) No 852/2004 and Regulation (EC) No 853/2004 should be amended accordingly.

(51) Regulation (EC) No 1099/2009[14] 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[15]. ~~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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[13] 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)

[14] 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)

[15] 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[16] 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[17] 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~~y~~**ies** 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.

(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~~ **BSE** risk ~~categories~~ **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

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[16] 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

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

ruminant collagen and gelatine derived from bones[18]. 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.

(57) Article 23 and 23a of Regulation (EC) No 999/2001 currently ~~empower the Commission to amend non-essential elements of this Regulation, including by supplementing it,~~ **provide that the Annexes to that Regulation may be amended or supplemented, and that certain technical measures may be adopted,** through the regulatory procedure with scrutiny referred to in Article 24(3). In order to achieve the objectives of Regulation (EC) No 999/2001 and ensure the timely adaptation to evolving epidemiological situations, scientific knowledge and international standards, ~~it is appropriate to replace these empowerments with delegated acts~~ **the power to amend the Annexes should be delegated to the Commission** in accordance with Article 290 of the Treaty. **The regulatory procedure with scrutiny should continue to apply only to the specific technical measures listed in Article 23a.** ~~The Commission should therefore be empowered to amend the annexes and to supplement that Regulation.~~, ~~I~~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[19] 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~~

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[18] 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

~~[19] 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)~~

~~consignment cannot be released until all the necessary checks for that consignment have been completed.~~

(58) Regulation (EU) 2017/625 establishes rules on the performance of official controls by the competent authorities of the Member States, among others, on animals and goods entering the Union in order to verify compliance with Union agri-food chain legislation. Article 50(3) of Regulation (EU) 2017/625 allows the splitting of consignments only after the completion of official controls and the finalisation of the Common Health Entry Document (CHED), which implies that a consignment cannot be released until all the necessary checks for that consignment have been completed.

(59) Consignments of goods falling under the rules referred to in Article 1(2)(g) of Regulation (EU) 2017/625 may consist of plants and plant products of different types, classes or descriptions, covered by the same official phytosanitary certificate. Due to the diversity of plants and plant products in the same consignment, each ~~item~~ **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**s** 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.

(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 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:

[…]

N.B. Articles 1-4 amend Regulations (EC) No 396/2005, (EC) No 1107/2009, (EU) No 528/2012 ('cluster B') and are addressed separately

Article 5
Amendment to Regulation (EC) No 1829/**2003**

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

~~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;** ~~F~~**f**ood and feed which are ~~obtained using as production strains~~ **produced with the assistance of** genetically modified micro-organisms ~~within the meaning of~~**as defined in** Art**icle** 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**:**

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

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

(i) it is ~~they are limited to~~ non-viable ~~cells,~~

(ii) its ~~their~~ presence is minimized through reasonable ~~**reasonably achievable**~~ attempts to remove **it** ~~them~~ in accordance with good manufacturing practice**;** and

(iii) it has ~~they have~~ no technological effect on the food or the feed~~.~~**;**'.

Article 6

Amendments to Regulation (EC) No 1831/2003

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

(-1) 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, ~~and~~ 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**, ~~and~~** 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, ~~and~~ premixtures and other feed containing them are ~~transferred~~ located until export:**

- **the mention "only for EXPORT – not ~~to be used as or in~~ for feeding animals in the EU";**
- **the designation of the feed additive, including the name of the active substances contained therein;**

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- **the name or business name and the address or registered place of business of the establishment producing and processing the additives, ~~and~~ premixtures and other feed containing them;**
- **where applicable, the approval number of the establishment producing and processing the additives, ~~and~~ 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 **is amended as follows:**

(a) paragraph 1 is replaced by the following:

'1. 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 **i**s ~~are~~ added:

'(o) ~~'label' means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on, or attached to the packaging or the container of the feed additive or premixture;~~

~~(p) 'labelling' means the attribution of any words, particulars, trade marks, brand name, pictorial matter or symbol to a feed additive or a premixture by placing this information on any medium referring to or accompanying such feed additive or premixture, such as packaging, container, notice, label, document, ring, collar or digital means, including for advertising purposes.';~~

~~(q)~~ 'holder of the authorisation' means the natural or legal person mentioned as such in the ~~Community~~ **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**s** 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*';

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* 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 = date of entry into force of this Regulation]* which include the name of the respective holder of the authorisation, in order to remove such name and include it in the Register. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 22(2).

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

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

'*Article 9a*

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

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

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

(b) urgent authorisations granted under Article 15;

(c) authorisations for which **the submission of an** ~~no~~ application for renewal **under Article 14(1) was required** ~~has been submitted by the deadline~~

~~set out in Article 14(1)~~ before *[OP: please insert the date = date of entry into force of this Regulation]* **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 = date of entry into force of this Regulation]* and for which no decision has been taken by that date.';

(6) Article 13 is replaced by the following:

'Article 13

Modification, suspension and revocation of authorisations

1. On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether an authorisation still meets the conditions set out in this Regulation, taking into account scientific and technological developments. In order to prepare its opinion, the Authority may, where appropriate, request the person who was the applicant for the authorisation concerned, or, where applicable, the holder of the authorisation, to submit within a specified time information and data relevant to the assessment **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).

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).

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 = date of entry into force of this Regulation*]

The procedures concerning the applications for renewal of authorisations submitted in accordance with Article 14 before [*OP: please insert the date = date of entry into force of this Regulation*] and for which no decision has been taken by that date, shall be completed in accordance with Article 14**, in the version in force on …** ~~as it stood before that date~~ **[date of entry into force of this amending 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[20]**;** ~~.~~

[20] 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).

(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**;**

(h) ~~and~~ **the** date of manufacture.

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

By way of derogation from the first subparagraph, the information referred to in points **(ba)**~~(b),~~ (d) and ~~(g)~~**(h)** 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

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minimum storage life shall be determined on the basis of the minimum storage life of each of its components.

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

7. The information provided by digital means shall be:

(a) made available on a physical ~~label~~ **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.

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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.';

(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(8)**, (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. 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 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 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.'.

(11) 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

In Regulation (EC) No 852/2004**,** ~~is amended as follows:~~

Article 13 is amended as follows:

(a) paragraph 3 is replaced by the following:

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

(b) paragraph 5 is replaced by the following:

'5. Any Member States wishing to adopt national measures referred to in paragraph 3 shall notify the Commission in accordance with the procedure laid down in Articles 5 and 6 of Directive (EU) 2015/1535. The notification shall:

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

(b) describe the foodstuffs and establishments concerned;

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

(d) provide any other relevant information.';

(c) paragraphs 6 and 7 are deleted.

Article 8
Amendment to Regulation (EC) No 853/2004

In 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

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to be taken to ensure that the adaptation will not compromise the objectives of this Regulation; and

(d) provide any other relevant information.';

(c) paragraphs 6 and 7 are deleted.

Article 9
Amendment of Regulation (EC) No 1099/2009

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

Article 10
Amendments to Regulation (EC) No 999/2001

Regulation (EC) 999/200**1**~~9~~ 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 **amending**~~approval of~~ the **list of approved** rapid tests **provided for** ~~and to amend the list set out~~ in Annex X, Chapter C, point 4';

(2) Article 6 is amended as follows:

(a) Paragraph 1 is replaced by the following:

'1. Each Member State shall carry out an annual monitoring programme for TSEs based on surveillance in accordance with Annex III.

The Commission is empowered to adopt delegated acts in accordance with Article 23b ~~for the purpose of approval of the rapid tests . The Commission is empowered to adopt delegated acts in accordance with Article 23b~~ amending **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

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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.;

(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:

'**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. ~~Paragraph 1 of this Article shall not apply to tissues from animals which have undergone the alternative test, provided that this test is applied under the conditions provided for in Annex V and the test results are negative.~~';

(c) paragraph 5 is replaced by the following:

'5. The Commission is empowered to adopt delegated acts in accordance with Article 23b to amend the rules providing exemptions from paragraphs 1 to 4 of this Article, with regard to the date of the effective enforcement of the feeding prohibition provided for in Article 7(1) or, as appropriate for third countries or

regions thereof with a controlled BSE risk, with regard to the date of the effective enforcement of the ban of ruminant protein in feed for ruminants with a view to limiting the requirements to remove and destroy specified risk material to animals born before that date in the countries or regions concerned.';

(4) Article 16 is amended as follows:

(a) **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 **by laying down detailed rules for the placing on the market of products of animal origin** ~~to adapt the provisions of~~ **referred to in** paragraphs 1 to 6 **of this Article**';

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

'**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).

2.~~3. Without prejudice to paragraphs 1 and 2, t~~**T**he Commission is empowered to adopt delegated acts in accordance with Article 23b **to** amend~~ing~~ 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 the **opinion of the European Food Safety** 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 power~~s~~ 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

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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
Amendments 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

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

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

'3. Consignments shall not be split until official controls have been performed and the Common Health Entry Document (CHED) referred to in Article 56 has been finalised in accordance with Article 56(5) and Article 57.~~,~~ **However,** ~~unless requested by the competent authorities~~ in the case of consignments of **plants, plant products, and other objects** ~~goods~~ referred to in Article 47(1) **points** (c) **, (e) and (f), competent authorities may request a split** ~~for the purposes of performing~~ **if the** physical checks on ~~only~~ part**s** of ~~a~~ **the** consignment **require more time than those on the remaining part, allowing for the release of that remaining part for which official controls have been completed**~~presented at a border control post.~~';

(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.';

[(2b) in Article 56, paragraph 1, the following second subparagraph is inserted:

'For wood packaging material as referred to in Article 43(1) of Regulation (EU) No 2016/2031 and for each consignment 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 CHED, providing the information necessary for the immediate and complete identification of the consignment and its destination.';

(2c) in Article 57, the following paragraph 4 is inserted:

'4. When the competent authorities of a Member State apply the provision of Article 56(1) second subparagraph, the provisions of paragraphs 2 and 3 apply mutatis mutandis.

Such provisions do not apply to consignments whose border control post of first arrival into the Union is in a Member State that does not apply the provision of Article 56(1), second subparagraph.']

(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 [18 months from the date of entry into force of this Regulation] the Commission shall adopt a delegated act in accordance with the first sub-paragraph, concerning the designation of reference laboratories in the area of protective measures against pests of plants.';

(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.';

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(b) paragraph 3 is replaced by the following:

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

(c) paragraph 6 is replaced by the following:

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

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Article 12

Entry into force and application

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

Article 1~~3~~**1, point** (4)(a)(ii)**,** shall apply from [*date of entry into force of this Regulation plus 2 years*] or from the date of the entry into force of the delegated act adopted in accordance with Article 100(6) of Regulation (EU) 2017/625 in the area of protective measures against pests of plants, whichever is the earliest.

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

Done at Strasbourg,

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

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