

Official Journal of the European Union

L 162



English edition

Legislation

Volume 64

10 May 2021

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2021/756 of 24 March 2021 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products ⁽¹⁾ 1**
- ★ **Commission Implementing Regulation (EU) 2021/757 of 3 May 2021 entering a name in the register of protected designations of origin and protected geographical indications ‘Ennstaler Steirerkas’ (PDO) 4**
- ★ **Commission Implementing Regulation (EU) 2021/758 of 7 May 2021 on the status of certain products as feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council and on the withdrawal from the market of certain feed additives ⁽¹⁾ 5**
- ★ **Commission Implementing Regulation (EU) 2021/759 of 7 May 2021 amending Implementing Regulation (EU) 2019/2072 as regards the exceptions from the requirement of a plant passport, the status of Italy, Ireland, Lithuania, Slovenia and Slovakia or certain areas thereof as protected zones, and the reference to a protected zone in Portugal 18**
- ★ **Commission Implementing Regulation (EU) 2021/760 of 7 May 2021 amending Implementing Regulations (EU) 2020/761 and (EU) 2020/1988 as regards the management system of some tariff quotas with licences and repealing Implementing Regulation (EU) 2020/991 25**
- ★ **Commission Implementing Regulation (EU) 2021/761 of 7 May 2021 amending Annexes I to IV to Implementing Regulation (EU) 2017/717 as regards the model forms of zootechnical certificates for breeding animals and their germinal products ⁽¹⁾ 46**

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

DECISIONS

- ★ **Commission Implementing Decision (EU) 2021/762 of 6 May 2021 concerning the extension of the action taken by the Irish Department of Agriculture, Food and the Marine permitting the making available on the market and use of biocidal products containing propan-2-ol for use as human hygiene products in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council** (*notified under document C(2021) 3127*) 50

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2021/756

of 24 March 2021

amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽¹⁾, and in particular Article 23b thereof,Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ⁽²⁾, and in particular Article 16a(3) thereof,

Whereas:

- (1) Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus (SARS-CoV-2). On 30 January 2020, the World Health Organization (WHO) declared the outbreak of COVID-19 a public health emergency of international concern. On 11 March 2020, it characterised COVID-19 as a pandemic.
- (2) The COVID-19 pandemic has given rise to an unprecedented public health emergency that has claimed hundred thousands of lives worldwide, affecting in particular older people and those with underlying or pre-existing health conditions.
- (3) COVID-19 is a complex disease that affects multiple physiological processes. COVID-19 vaccines are considered an efficient medical countermeasure during the ongoing pandemic, for the protection of particularly vulnerable groups and the population as a whole.
- (4) Based on the scientific assessment by the European Medicines Agency, the Commission has thus far authorised several COVID-19 vaccines.
- (5) Mutations of the SARS-CoV-2 virus are a natural phenomenon and to be expected. Authorised vaccines are not necessarily less effective against mutations, but there is a risk that they may be.
- (6) In order to ensure the continued effectiveness of authorised COVID-19 vaccines, it may be necessary to modify them in ways that involve changing their composition so as to protect against new or multiple variant strains in the context of the pandemic or otherwise. Such changes, which include the replacement or addition of a serotype,

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.⁽²⁾ OJ L 136, 30.4.2004, p. 1.

strain or antigen or a combination of serotypes, strains or antigens, should be considered as variations to the marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008 ⁽⁷⁾. Some vaccines are based on nucleic acid technology to produce an immune response. Modifications of those vaccines may include changes to the coding sequence.

- (7) The same approach should be followed for all human coronaviruses.
- (8) The provisions on such variations should be streamlined, especially during a pandemic. In line with the approach taken with human influenza vaccines, the procedures should apply to all human coronavirus vaccines and follow an accelerated timetable. However, where the competent authorities request additional data in the course of their assessment, they should not be required to take a decision until the assessment of that data has been finalised.
- (9) During a pandemic, it may be in the interest of public health to process variations on the basis of less comprehensive data than is normally the case. However, this approach should be subject to a requirement that the data be complemented subsequently, with a view to confirming that benefit-risk balance remains favourable.
- (10) Regulation (EC) No 1234/2008 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1234/2008 is amended as follows:

- (1) Article 21 is replaced by the following

'Article 21

Pandemic situation with respect to human influenza and human coronavirus

- (1) By way of derogation from Chapters I, II, IIa and III, where a pandemic situation with respect to human influenza or human coronavirus is duly recognised by the World Health Organization or by the Union in the framework of Decision No 1082/2013/EU of the European Parliament and of the Council (*), the relevant authorities, or in the case of centralised marketing authorisations, the Commission may, where certain pharmaceutical, non-clinical or clinical data are missing, exceptionally and temporarily accept a variation to the terms of a marketing authorisation for a human influenza vaccine or a human coronavirus vaccine.
- (2) The relevant authority may request the applicant to provide supplementary information in order to complete its assessment within a time limit set by it.
- (3) Variations may be accepted pursuant to paragraph 1 only if the benefit-risk balance of the medicinal product is favourable.
- (4) Where a variation is accepted pursuant to paragraph 1, the holder shall submit the missing pharmaceutical, non-clinical and clinical data within a time limit set by the relevant authority.

⁽⁷⁾ Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).

(5) In the case of centralised marketing authorisations, the missing data and the time limit for submission or compliance shall be specified in the conditions to the marketing authorisation. Where the marketing authorisation has been granted in accordance with Article 14-a of Regulation (EC) No 726/2004 this may be done as part of the specific obligations referred to in paragraph 4 of that Article.

(*) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).'

(2) In point (a) of Article 23(1a) the following point (ix) is added:

‘(ix) variations related to changes to the active substance of a human coronavirus vaccine, including replacement or addition of a serotype, strain, antigen or coding sequence or combination of serotypes, strains, antigens or coding sequences;’

(3) In point 1 of Annex I, point (c) is replaced by the following:

‘(c) replacement of a biological active substance with one of a slightly different molecular structure where the efficacy and/or safety characteristics are not significantly different, with the exception of:

- changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza;
- replacement or addition of a serotype, strain, antigen or coding sequence or combination of serotypes, strains, antigens or coding sequences for a human coronavirus vaccine;
- replacement or addition of a serotype, strain, antigen or combination of serotypes, strains or antigens for a veterinary vaccine against avian influenza, foot-and-mouth disease or bluetongue;
- replacement of a strain for a veterinary vaccine against equine influenza;’

(4) In point 2 of Annex II the following point (l) is added:

‘(l) variations related to the replacement or addition of a serotype, strain, antigen or coding sequence or combination of serotypes, strains, antigens or coding sequences for a human coronavirus vaccine.’

Article 2

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

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

Done at Brussels, 24 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2021/757**of 3 May 2021****entering a name in the register of protected designations of origin and protected geographical indications 'Ennstaler Steirerkas' (PDO)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Austria's application to register the name 'Ennstaler Steirerkas' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Ennstaler Steirerkas' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Ennstaler Steirerkas' (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.3 – Cheeses, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.

Article 2

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

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

Done at Brussels, 3 May 2021.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ OJ C 20, 19.1.2021, p. 11.

⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

COMMISSION IMPLEMENTING REGULATION (EU) 2021/758**of 7 May 2021****on the status of certain products as feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council and on the withdrawal from the market of certain feed additives****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Articles 2(3) and 10(5) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. In particular, Article 10(2), in conjunction with Article 10(7) of that Regulation provides for specific procedures for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾ and Council Directive 82/471/EEC ⁽³⁾.
- (2) Article 10(5) of Regulation (EC) No 1831/2003 imposes an obligation on the Commission to adopt a Regulation withdrawing from the market feed additives for which no notification referred to in Article 10(1)(a) of that Regulation was supplied within a specified period. The same obligation applies to feed additives for which no applications in accordance with Article 10(2) and (7) of Regulation (EC) No 1831/2003 were submitted before the deadline provided for in those provisions, or for which an application was submitted but subsequently withdrawn.
- (3) Therefore, such feed additives should be withdrawn from the market. As Article 10(5) of Regulation (EC) No 1831/2003 does not differentiate between authorisations issued with a time limit and authorisations without a time limit, for clarity reasons it is appropriate to provide for the withdrawal from the market of feed additives whose limited authorisation periods pursuant to Directive 70/524/EEC have already expired.
- (4) In the case of feed additives for which applications have been submitted only for certain animal species or categories of animals, or applications have been withdrawn only for certain animal species or categories of animals, the withdrawal from the market should only concern the animal species and categories of animals for which no application has been submitted or the application has been withdrawn.
- (5) As a consequence of the withdrawal from the market of the feed additives, it is appropriate to repeal the provisions authorising them, where such provisions are still in force. Consequently, Commission Regulation (EC) No 358/2005 ⁽⁴⁾ should be amended accordingly. In addition, Commission Regulation (EC) No 880/2004 ⁽⁵⁾ should be repealed, as both entries in the Annex thereto are to be deleted as a result of the withdrawal from the market of

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (OJ L 213, 21.7.1982, p. 8).

⁽⁴⁾ Commission Regulation (EC) No 358/2005 of 2 March 2005 concerning the authorisation without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs (OJ L 57, 3.3.2005, p. 3).

⁽⁵⁾ Commission Regulation (EC) No 880/2004 of 29 April 2004 authorising without time limit the use of beta carotene and canthaxanthin as additives in feedingstuffs belonging to the group of colouring matters including pigments (OJ L 162, 30.4.2004, p. 68).

beta-carotene for use for canaries as provided in Annex I, Chapter I.A, part 2, and as a result of the authorisation of canthaxanthin for use for ornamental birds in Commission Implementing Regulation (EU) 2015/1486 ⁽⁶⁾. Furthermore, as a consequence of both the authorisation of canthaxanthin by Implementing Regulation (EU) 2015/1486 and the withdrawal from the market of that additive for non-authorised species and uses by Commission Implementing Regulation (EU) 2017/1145 ⁽⁷⁾, it is appropriate to repeal Commission Regulation (EC) No 775/2008 ⁽⁸⁾ which established maximum residue limits for canthaxanthin.

- (6) As regards feed additives whose authorisation did not expire until the date of entry into force of this Regulation, it is appropriate to allow a transitional period for interested parties, within which existing stocks of the additives concerned, premixtures, feed materials and compound feed which have been produced with those additives may be used up, taking account of the shelf-life of certain feed containing the additives in question.
- (7) The withdrawal from the market of the products listed in Annex I does not prevent them from being authorised or subject to a measure concerning their status in accordance with Regulation (EC) No 1831/2003.
- (8) For several substances, micro-organisms or preparations (referred to as 'products'), there is uncertainty whether they are feed additives within the scope of Regulation (EC) No 1831/2003. This uncertainty may result from the inclusion of certain products both in the Register of feed additives referred to in Article 17 of Regulation (EC) No 1831/2003 and in the Catalogue of feed materials established in accordance with Article 24 of Regulation (EC) No 767/2009 of the European Parliament and of the Council ⁽⁹⁾. The uncertainty may also derive from various doubts or questions expressed by national competent authorities responsible for official controls or by economic operators concerning the classification of certain products, taking into account in particular the guidelines established by Commission Recommendation 2011/25/EU ⁽¹⁰⁾.
- (9) Such uncertainty about the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 may jeopardise the marketing of feed products throughout the Union, since the distinction between feed additives and other feed products has implications for the conditions of their placing on the market, depending on the relevant applicable legislation.
- (10) In order to allay the uncertainty regarding the status as feed additives of certain products, it is appropriate to adopt relevant measures under Regulation (EC) No 1831/2003, clarifying that status. Such measures would bring consistency in the treatment of the products concerned and would facilitate the work of the national competent authorities responsible for official controls, while helping the interested economic operators to act in a framework providing for an appropriate level of legal certainty.
- (11) To determine whether products are feed additives within the scope of Regulation (EC) No 1831/2003, it is appropriate to refer to the guidelines for the distinction between feed additives, feed materials and other products, established by Recommendation 2011/25/EU. In particular, those guidelines provide for several criteria to be simultaneously considered in a case-by-case evaluation in order to create a profile of each specific product, taking

⁽⁶⁾ Commission Implementing Regulation (EU) 2015/1486 of 2 September 2015 concerning the authorisation of canthaxanthin as feed additive for certain categories of poultry, ornamental fish and ornamental birds (OJ L 229, 3.9.2015, p. 5).

⁽⁷⁾ Commission Implementing Regulation (EU) 2017/1145 of 8 June 2017 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives (OJ L 166, 29.6.2017, p. 1).

⁽⁸⁾ Commission Regulation (EC) No 775/2008 of 4 August 2008 establishing maximum residue limits for the feed additive canthaxanthin in addition to the conditions provided for in Directive 2003/7/EC (OJ L 207, 5.8.2008, p. 5).

⁽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).

⁽¹⁰⁾ Commission Recommendation 2011/25/EU of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products (OJ L 11, 15.1.2011, p. 75).

into account all its characteristics. Useful criteria for the differentiation between feed additives and feed materials include the production and processing method, the chemical definition and the level of standardisation or purification, the safety conditions and mode of use, the functionality of the product concerned. In addition, for the sake of consistency, products with similar properties should be classified by analogy.

- (12) The products sodium citrates, potassium citrates, sorbitol, mannitol and calcium hydroxide are included in the Register of feed additives as existing products for which no applications in accordance with Article 10(2) of Regulation (EC) No 1831/2003 were submitted before the deadline prescribed by that provision. They have also been included in the Catalogue of feed materials by Commission Regulation (EU) No 575/2011 ⁽¹¹⁾. However, a re-examination of the profile of those products with regard to the criteria proposed in Recommendation 2011/25/EU led to the conclusion that they should be considered as feed additives within the scope of Regulation (EC) No 1831/2003. In particular, they are defined by their specific functions referred to in the Register of feed additives and their feed additives status allows improved scope for an effective management thereof in terms of safety and mode of use. In addition, account is taken of their classification as additives for use in food.
- (13) The feed additives status of the products sodium citrates, potassium citrates, sorbitol, mannitol and calcium hydroxide makes it necessary to withdraw them from the market as provided for by Article 10(5) of Regulation (EC) No 1831/2003. However, a longer transitional period should be allowed for the withdrawal from the market of those additives and of feed containing them, in order to take account of the legal uncertainty about their classification, allowing interested parties to submit a new application for authorisation of those feed additives under the procedures set out in Regulation (EC) No 1831/2003.
- (14) Most of the products listed in Annex II are included in the Catalogue of feed materials established by Commission Regulation (EU) No 68/2013 ⁽¹²⁾. However, they are all, in addition, either listed in the Register of feed additives or have been subject to a withdrawal from the market as feed additives under Article 10(5) of Regulation (EC) No 1831/2003. In order to provide legal certainty concerning the status of those products, their respective profiles were examined in the light of the criteria proposed in Recommendation 2011/25/EU, leading to the conclusion that they should no longer be considered as feed additives within the scope of Regulation (EC) No 1831/2003.
- (15) As regards the labelling of the products listed in Annex II which are still allowed on the market as feed additives, and the labelling of premixtures, feed materials and compound feed containing those products, a transitional period should be provided for to allow feed business operators to adapt. Furthermore, those products should be deleted from the Register of feed additives.
- (16) The products xylitol, ammonium lactate and ammonium acetate are included in the Catalogue of feed materials established by Regulation (EU) No 68/2013. However, some doubts have been expressed notably by national competent authorities responsible for official controls as to their legal status, which led to an examination of their respective profiles based on the criteria proposed in Recommendation 2011/25/EU. Based on that examination, it has been concluded that those products should be considered as feed additives within the scope of Regulation (EC) No 1831/2003. In particular, the characteristics of xylitol are very similar to those of mannitol and sorbitol, which are considered as feed additives, and the classification of xylitol as a feed additive by analogy would bring consistency in the treatment of those similar products. In addition, account is taken of the classification of xylitol as

⁽¹¹⁾ Commission Regulation (EU) No 575/2011 of 16 June 2011 on the Catalogue of feed materials (OJ L 159, 17.6.2011, p. 25).

⁽¹²⁾ Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1).

additive for use in food. As regards ammonium lactate and ammonium acetate, they are chemically well-defined substances that are purified and exerting a specific function defined in Article 5(3) of Regulation (EC) No 1831/2003 and their feed additives status allows improved scope for an effective management thereof in terms of safety and mode of use. Moreover, a classification of ammonium lactate and ammonium acetate as feed additives would bring consistency with other similar products considered as feed additives, such as ammonium propionate or ammonium formate.

- (17) As a result of the classification of xylitol, ammonium lactate and ammonium acetate as feed additives within the scope of Regulation (EC) No 1831/2003, it is appropriate to provide for a transitional period which would allow interested parties to adapt to the new status of those products, including the submission of an application for authorisation, and the further processing thereof, under the procedures set out in Regulation (EC) No 1831/2003.
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Withdrawal from the market

The feed additives specified in Annex I shall be withdrawn from the market in respect of the animal species or categories of animals as specified in that Annex.

Article 2

Transitional measures for the feed additives to be withdrawn from the market

1. Existing stocks of the feed additives listed in Chapters I.A and I.C of Annex I may continue to be placed on the market and used until 30 May 2022.
2. Premixtures produced with the additives referred to in paragraph 1 may continue to be placed on the market and used until 30 August 2022.
3. Compound feed and feed materials produced with the additives referred to in paragraph 1 or with the premixtures referred to in paragraph 2 may continue to be placed on the market and used until 30 May 2023.
4. By way of derogation from paragraphs 1, 2 and 3, the feed additives sodium citrates, potassium citrates, sorbitol, mannitol and calcium hydroxide listed in Chapter I.A of Annex I, and feed produced with those additives, may continue to be placed on the market and used until 30 May 2028.

Article 3

Amendment to Regulation (EC) No 358/2005

In Annex II to Regulation (EC) No 358/2005, entry E 141 on chlorophyll copper complex is deleted.

Article 4

Repeals

Regulations (EC) No 880/2004 and (EC) No 775/2008 are repealed.

*Article 5***Products not considered as feed additives within the scope of Regulation (EC) No 1831/2003**

1. The substances, micro-organisms or preparations (referred to as 'products') set out in Annex II are not feed additives within the scope of Regulation (EC) No 1831/2003.
2. Products referred to in paragraph 1 which are lawfully on the market and are labelled as feed additives and premixtures before 30 May 2024 may continue to be placed on the market until stocks are exhausted. The same applies to feed materials or compound feed which refer to those products in their labelling as feed additives in accordance with Regulation (EC) No 767/2009.

*Article 6***Products considered as feed additives within the scope of Regulation (EC) No 1831/2003**

1. The substances, micro-organisms or preparations (referred to as 'products') set out in Annex III are feed additives within the scope of Regulation (EC) No 1831/2003.
2. Products referred to in paragraph 1 may continue to be placed on the market and used until 30 May 2028.

*Article 7***Entry into force**

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

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

Done at Brussels, 7 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Feed additives to be withdrawn from the market, as referred to in Article 1

CHAPTER I.A.

Feed additives which were authorised without a time limit

Part 1

Feed additives to be withdrawn from the market for all species and categories of animals

Identification Number	Additive	Species or category of animals
Preservatives		
E 331	Sodium citrates	All species
E 332	Potassium citrates	All species
E 325	Sodium lactate	All species
E 326	Potassium lactate	All species
Emulsifying and stabilising agents, thickeners and gelling agents		
E 420	Sorbitol	All species
E 421	Mannitol	All species
Binders, anti-caking agents and coagulants		
E 558	Bentonite-montmorillonite	All species
Vitamins, provitamins and chemically well-defined substances having similar effect		
	Riboflavin or Vitamin B ₂ . All forms with the exception of : — Riboflavin solid form produced by <i>Ashbya gossypii</i> DSM 23096 ⁽¹⁾ [3a825i]; — Riboflavin solid form produced by <i>Bacillus subtilis</i> DSM 17339 and/or DSM 23984 ⁽¹⁾ [3a825ii]; — Riboflavin 5'-phosphate ester monosodium salt solid form produced after phosphorylation of riboflavin 98 % produced by <i>Bacillus subtilis</i> DSM 17339 and/or DSM 23984 ⁽¹⁾ [3a826]; — Riboflavin (80 %) produced by <i>Bacillus subtilis</i> KCCM-10445 ⁽²⁾ .	All species
E 160 a	Beta-carotene. All forms with the exception of beta-carotene authorised by Commission Implementing Regulation (EU) 2015/1103 ⁽³⁾ [3a160(a)]	All species
Silage additives		
Microorganisms		
	<i>Enterococcus faecium</i> CNCM I-3236/ATCC 19434	All species
	<i>Bacillus subtilis</i> MBS-BS-01	All species
	<i>Lactobacillus plantarum</i> DSM 11520	All species
Colourants, including pigments		
Other colourants		
E 153	Carbon black as a colouring agent authorised for colouring foodstuffs by Community rules	All species
Flavouring and appetising substances		
Natural products – botanically defined		

Identification Number	Additive	Species or category of animals
	<i>Allium cepa</i> L.: Onion concentrate CoE 24	All species
	<i>Allium sativum</i> L.: Garlic extract (water-based)	All species
	<i>Amyris balsamifera</i> L.: Amyris oil CoE 33	All species
	<i>Anacardium occidentale</i> L.: Cashew oil CoE 34	All species
	<i>Anethum graveolens</i> L.: Dill seed extract CAS 8006-75-5 CoE 42 EINECS 289-790-8	All species
	<i>Apium graveolens</i> L.: Celery seed extract CAS 89997-35-3 FEMA 2270 CoE 52 EINECS 289-668-4	All species
	<i>Artemisia absinthium</i> L.: Wormwood oil CAS 8008-93-3 FEMA 3116 CoE 61 EINECS 284-503-2	All species
	<i>Artemisia annua</i> L.: Annual mugwort extract (water-based)/Annual mugwort oil	All species
	<i>Artemisia pallens</i> Wall.: Davana oil CAS 8016-03-3 FEMA 2359 CoE 69 EINECS 295-155-6	All species
	<i>Bacopa monnieri</i> (L.) Pennell: Thyme leaved gratiola tincture	All species
	<i>Carum carvi</i> L. = <i>Apium carvi</i> L.: Caraway seed extract/Caraway oleoresin CAS 8000-42-8 CoE 112 EINECS 288-921-6	All species
	<i>Cimicifuga simplex</i> (Wormsk. ex DC.) Ledeb. = <i>C. racemosa</i> (L.) Nutt.: Sarashina shoma extract	All species
	<i>Cinnamomum aromaticum</i> Nees, <i>C. cassia</i> Nees ex Blume: Cassia bark extract CAS 84961-46-6 FEMA 2257 CoE 131 EINECS 284-635-0	All species
	<i>Cinnamomum zeylanicum</i> Bl., <i>C. verum</i> J.S. Presl: Cinnamon bark oleoresin CAS 84961-46-6 FEMA 2290 CoE 133 EINECS 283-479-0	All species
	<i>Citrus aurantium</i> L.: Neroli bigarade oil CAS 8016-38-4 FEMA 2771 CoE 136 EINECS 277-143-2/Petitgrain bigarade absolute CAS 8014-17-3 CoE 136 EINECS 283-881-6	All species
	<i>Citrus reticulata</i> Blanco: Mandarin, Tangerine terpenes CoE 142	All species
	<i>Citrus x paradisi</i> Macfad.: Grapefruit oil expressed CAS 8016-20-4 FEMA 2530 CoE 140 EINECS 289-904-6/Grapefruit extract CoE 140	All species
	<i>Glycyrrhiza glabra</i> L.: Licorice extract (solvent-based) CAS 97676-23-8 FEMA 2628 CoE 218 EINECS 272-837-1	All species
	<i>Juniperus communis</i> L.: Juniper berry extract CAS 84603-69-0 CoE 249 EINECS 283-268-3	All species
	<i>Laurus nobilis</i> L.: Laurel leaves extract/Laurel leaves oleoresin CAS 84603-73-6 FEMA 2613 CoE 255 EINECS 283-272-5	All species
	<i>Lavandula latifolia</i> Medik.: Spike lavender oil CoE 256	All species
	<i>Lepidium meyenii</i> Walp.: Maca extract	All species
	<i>Leptospermum scoparium</i> J. R. et G. Forst.: Broom teatree oil	All species
	<i>Macleaya cordata</i> (Willd.) R. Br.: Plume poppy absolute/Plume poppy extract/Plume poppy oil/Plume poppy tincture	All species
	<i>Mallotus philippinensis</i> (Lam.) Muell. Arg.: Kamala extract CoE 535	All species
	<i>Malpighia glabra</i> L.: Acerola extract	All species
	<i>Malus sylvestris</i> Mill.: Apple concentrate CoE 386	All species

Identification Number	Additive	Species or category of animals
	<i>Medicago sativa</i> L.: Alfalfa tincture CoE 274	All species
	<i>Melissa officinalis</i> L.: Melissa oil CoE 280	All species
	<i>Mentha pulegium</i> L.: Pennyroyal oil CAS 8013-99-8 FEMA 2839 CoE 283 EINECS 290-061-1	All species
	<i>Myristica fragrans</i> Houtt.: Mace oil CAS 8007-12-3 FEMA 2653 CoE 296 EINECS 282-013-3/Nutmeg oleoresin CAS 8408268-8 CoE 296 EINECS 282-013-3	All species
	<i>Myroxylon balsamum</i> (L.) Harms: Tolu balsam extract (solvent-based) CAS 9000-64-0 FEMA 3069 CoE 297 EINECS 232-550-4	All species
	<i>Myroxylon balsamum</i> (L.) Harms var. <i>Pereirae</i> : Balsam peru extract (solvent-based) CAS 8007-00-9 FEMA 2117, 2116 CoE 298 EINECS 232-352-8	All species
	<i>Ocimum basilicum</i> L.: Basil oil CAS 801573-4 FEMA 2119 CoE 308 EINECS 283-900-8	All species
	<i>Opopanax chironium</i> (L.) Koch, <i>Commiphora erythrea</i> Engler: Opopanax oil CAS 8021-36-1 CoE 313 EINECS 232-558-8	All species
	<i>Passiflora edulis</i> Sims. = <i>P. incarnata</i> L.: Passionfruit extract (water-based) CoE 321	All species
	<i>Pelargonium asperum</i> Her. ex Spreng.: Geranium oil	All species
	<i>Peumus boldus</i> Mol.: Boldo extract CoE 328/Boldo tincture CoE 328	All species
	<i>Pinus pinaster</i> Soland.: Pine oil	All species
	<i>Pimenta racemosa</i> (Mill.) J.W.Moore: Bay oil CAS 8006-78-8 CoE 334	All species
	<i>Piper methysticum</i> G. Forst.: Kava-kava tincture	All species
	<i>Quillaja saponaria</i> Molina: Quillaia extract (solvent-based) CoE 391/Quillaia concentrate	All species
	<i>Ribes nigrum</i> L.: Black currant extract CoE 399	All species
	<i>Satureja hortensis</i> L.: Savory summer oil CAS 8016-68-0 FEMA 3013 CoE 425 EINECS 283-922-8	All species
	<i>Sophora japonica</i> L.: Pagoda tree oil	All species
	<i>Styrax benzoin</i> Dryand., <i>S. tonkinensis</i> (Pierre) Craib ex Hartwich: Benzoin resinoid CAS 9000-05-9 FEMA 2133 CoE 439 EINECS 232-523-7	All species
	<i>Tagetes erecta</i> L., <i>T. glandulifera</i> Schrank., <i>T. minuta</i> L. e.a.: Tagetes oil CAS 8016- 84-0 FEMA 3040 CoE 443/494 EINECS 294-862-7	All species
	<i>Thea sinensis</i> L. = <i>Camellia thea</i> Link. = <i>Camellia sinensis</i> (L.) O. Kuntze: Tea tincture CoE 451	All species
	<i>Uncaria tomentosa</i> L. = <i>Ouroparia guianensis</i> Aubl.: Cat's claw extract	All species
	<i>Valeriana officinalis</i> L.: Valerian root tincture CoE 473	All species
	<i>Vetiveria zizanioides</i> (L.) Nash.: Vetiver oil CAS 8016-96-4 CoE 479 EINECS 282-490-8	All species

Identification Number	Additive	Species or category of animals
	<i>Vitis vinifera</i> L.: Cognac oil green CAS 8016-21-5 FEMA 2331 CoE 485 EINECS 232-403-4/Cognac oil white CAS 801621-5 FEMA 2332 CoE 485 EINECS 232-403-4	All species
	<i>Vitis vinifera</i> L.: Grape seed extract CoE 485	All species
	<i>Yucca mohavensis</i> Sarg. = <i>Y. schidigera</i> Roez. ex Ortgies: Mojave yucca extract (solvent-based) CAS 90147-57-2 FEMA 3121 EINECS 290-449-0/Yucca concentrate/Yucca residuals	All species
	<i>Zingiber officinale</i> Rosc.: Ginger extract CAS 84696-15-1 FEMA 2521 CoE 489 EINECS 283-634-2	All species

Natural products and corresponding synthetic products

	CAS No 1128-08-1/3-Methyl-2-pentylcyclopent-2-en-1-one/Flavis No 07.140	All species
	CAS No 352195-40-5/Disodium Inosine-5-Mono-phosphate (IMP)	All species

(¹) Those forms of riboflavin have been authorised by Commission Implementing Regulation (EU) 2019/901 of 29 May 2019 concerning the authorisation of riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) (sources of vitamin B2) as feed additives for all animal species (OJ L 144, 3.6.2019, p. 41).

(²) This form of riboflavin has been the subject of a denial of authorisation by Commission Implementing Regulation (EU) 2018/1254 of 19 September 2018 concerning the denial of authorisation of riboflavin (80 %) produced by *Bacillus subtilis* KCCM-10445 as a feed additive belonging to the functional group of vitamins, pro-vitamins and chemically well-defined substances having similar effect (OJ L 237, 20.9.2018, p. 5).

(³) Commission Implementing Regulation (EU) 2015/1103 of 8 July 2015 concerning the authorisation of beta-carotene as a feed additive for all animal species (OJ L 181, 9.7.2015, p. 57).

Part 2

Feed additives to be withdrawn from the market for certain species or categories of animals

Identification Number	Additive	Species and category of animals
-----------------------	----------	---------------------------------

Trace elements

E 7	Molybdenum – Mo, Sodium molybdate	All animal species and categories with the exception of sheep
-----	-----------------------------------	---

Acidity regulators

E 503 (i)	Ammonium carbonate	Cats; Dogs
E 503 (ii)	Ammonium hydrogen carbonate	Cats; Dogs
E 525	Potassium hydroxide	Cats; Dogs
E 526	Calcium hydroxide	Cats; Dogs

Colourants, including pigments

Carotenoids and xanthophylls

E 160 a	Beta-carotene	Canaries
---------	---------------	----------

Identification Number	Additive	Species and category of animals
Other colourants		
E 141	Chlorophyllin copper complex as a colouring agent authorised for colouring foodstuffs by Community rules	All animal species and categories with the exception of dogs and cats
E 141	Chlorophyll copper complex as a colouring agent [functional group 2 a (iii)]	Grain-eating ornamental birds; Small rodents; Ornamental fish
E 153	Carbon black as a colouring agent [functional group 2 a (iii)]	Ornamental fish
E 172	Iron Oxide Red, Black & Yellow as colouring agent authorised for colouring foodstuffs by Community rules	Horses
Flavouring and appetising substances		
Natural products – botanically defined		
	<i>Helianthus annuus</i> L.: Sunflower extract	Cats; Dogs
	<i>Hyssopus officinalis</i> L. = <i>H. decumbens</i> Jord. & Fourr.: Hyssop Oil CAS 8006-83-5 FEMA 2591 CoE 235 EINECS 283-266-3	Cats; Dogs
	<i>Sus scrofa</i> (extract from defatted porcine pancreatic glands)	Cats and dogs and other carnivorous and omnivorous companion animals such as ferrets
Amino acids, their salts and analogues		
3.2.7.	Mixtures of: (a) L-lysine-monohydrochloride, technically pure and, (b) DL-methionine, technically pure protected with copolymer vinyl-pyridine/styrene	Dairy cows

CHAPTER I.B.

Feed additives which were authorised for a limited period

Identification Number	Additive	Species or category of animals
Coccidiostats and other medicinal substances		
E 758	Robenidine hydrochloride 66 g/kg (holder of the authorisation Zoetis Belgium SA)	Turkeys
E 770	Maduramicin ammonium alpha 1 g/100 g (holder of the authorisation Zoetis Belgium SA)	Turkeys

CHAPTER I.C.

Feed additives for which a notification referred to in Article 10(1)(a) of Regulation (EC) No 1831/2003 was not submitted

Identification Number	Additive	Species or category of animals
Amino acids, their salts and analogues		
3.2.6.	L-lysine phosphate and its by-products produced by fermentation with <i>Brevibacterium lactofermentum</i> NRRL B-11470	Poultry; Pigs

ANNEX II

Products which are not feed additives within the scope of Regulation (EC) No 1831/2003, as referred to in Article 5(1)

1. Tamarind seed flour
 2. Potassium dihydrogen orthophosphate
 3. Dipotassium hydrogen orthophosphate
 4. Tripotassium orthophosphate
 5. Ammonium dihydrogen orthophosphate
 6. Diammonium hydrogen orthophosphate
 7. Disodium dihydrogen diphosphate
 8. Tetrapotassium diphosphate
 9. Pentapotassium triphosphate
 10. Sodium sesquicarbonate
 11. Potassium hydrogen carbonate
 12. Calcium oxide
 13. Sucrose esters of fatty acids (esters of saccharose and edible fatty acids)
 14. Sucroglycerides (mixture of esters of saccharose and mono- and di-glycerides of edible fatty acids)
 15. Polyglycerol esters of non-polymerised edible fatty acids
 16. Mono-esters of propane-1,2-diol (propyleneglycol) and edible fatty acids, alone or in mixtures with diesters
 17. *Merluccius capensis*, *Galeorhinus australis* e.a.,/Cartilage
-

*ANNEX III***Products which are feed additives within the scope of Regulation (EC) No 1831/2003, as referred to in Article 6(1)**

1. Xylitol
 2. Ammonium lactate
 3. Ammonium acetate
-

COMMISSION IMPLEMENTING REGULATION (EU) 2021/759**of 7 May 2021****amending Implementing Regulation (EU) 2019/2072 as regards the exceptions from the requirement of a plant passport, the status of Italy, Ireland, Lithuania, Slovenia and Slovakia or certain areas thereof as protected zones, and the reference to a protected zone in Portugal**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/2031 of the European Parliament and 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 ⁽¹⁾, and in particular Article 32(3) and (6), Article 35(1) and (2), and Article 79(2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2019/2072 ⁽²⁾ established rules concerning plant passports for the movement within the Union of plants, plant products and other objects. Moreover, in Annex III, that Regulation recognised certain Member States and areas in Member States as protected zones in respect of certain protected zone quarantine pests. Furthermore, certain protected zones were recognised as temporary protected zones until 30 April 2020, in order to allow each Member State concerned to provide all information necessary to show that the pests concerned did not occur in the Member State or area concerned, or to complete or continue the efforts to eradicate the pest concerned.
- (2) Experience has shown that the scope of certain rules concerning exceptions from the requirement of a plant passport, as set out in Article 13(2)(b) of Implementing Regulation (EU) 2019/2072, should be extended. In particular, for reasons of consistency and in order to cover all cases of regulated plants, plant products and other objects, such exceptions should also cover seeds of plants, plant products and other objects that are not subject to the implementing acts adopted pursuant to Articles 28(1), 30(1) or 49(1) of Regulation (EU) 2016/2031.
- (3) For Italy, the territory of Campania and that of certain parts of Piedmont were recognised as a protected zone with respect to *Erwinia amylovora* (Burr.) Winsl. *et al.* In 2020, Italy submitted information showing that *Erwinia amylovora* (Burr.) Winsl. *et al.* is now established in the municipalities of Agerola, Gragnano, Lettere, Pimonte and Vico Equense in the province of Naples, and Amalfi, Atrani, Conca dei Marini, Corbara, Furore, Maiori, Minori, Positano, Praiano, Ravello, Scala and Tramonti in the province of Salerno, and in the entire territory of Piedmont. Those municipalities and the entire territory of Piedmont should therefore no longer be recognised as part of the protected zone in respect of *Erwinia amylovora* (Burr.) Winsl. *et al.*
- (4) Furthermore, certain parts of the territory of Italy were recognised as a temporary protected zone with respect to *Erwinia amylovora* (Burr.) Winsl. *et al.* until 30 April 2020. From survey results provided by Italy in 2019 and 2020, it appears that the protected zone quarantine pest, which was found in sporadic and isolated outbreaks in some parts of the protected zone, has been either eradicated or is under eradication and that the remaining parts of the protected zone continues to be free from that pest. That information also shows that so far none of the eradications has lasted more than two years. Therefore, the recognition of those parts of the territory of Italy as a protected zone in respect of *Erwinia amylovora* (Burr.) Winsl. *et al.* should be continued without any time limitation.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

- (5) The territories of Ireland, Lithuania, Slovenia and Slovakia were recognised as temporary protected zones with respect to *Erwinia amylovora* (Burr.) Winsl. *et al.* until 30 April 2020. From survey results provided by Ireland, Lithuania, Slovenia and Slovakia in 2019 and 2020, it appears that the protected zone quarantine pest, which was found in sporadic and isolated outbreaks in some parts of the protected zones, has been either eradicated or is under eradication and that the rest of the protected zone continues to be free from that pest. That information also shows that so far none of the outbreak eradications has lasted more than two years. Therefore, the recognition of the territories of Ireland, Lithuania, Slovenia and Slovakia as protected zones in respect of *Erwinia amylovora* (Burr.) Winsl. *et al.* should be continued without any time limitation.
- (6) Furthermore, in 2020, Slovakia submitted information showing that *Erwinia amylovora* (Burr.) Winsl. *et al.* is now established in the townships of Valice, Jesenské and Rimavská Sobota in the Rimavská Sobota County. Those townships should therefore no longer be recognised as part of the protected zone in respect of *Erwinia amylovora* (Burr.) Winsl. *et al.*
- (7) Ireland requested that its territory be recognised as a protected zone in respect of *Thaumetopoea pityocampa* Denis & Schiffermüller. On the basis of surveys conducted in 2018 and 2019, Ireland submitted evidence that the pest concerned does not occur in its territory, despite the existence of favourable conditions for that pest there. It is, however, necessary that further surveys be carried out. Therefore, Ireland should be recognised as a temporary protected zone in respect of *Thaumetopoea pityocampa* Denis & Schiffermüller until 30 April 2023.
- (8) For the purpose of consistency with the amendments of Annex III to Implementing Regulation (EU) 2019/2072, which lists the protected zones and the respective protected zone quarantine pests, the corresponding changes should be made to Annexes IX and X to that Regulation, which list the plants, plant products and other objects whose introduction into certain protected zones is prohibited and the plants, plant products and other objects to be introduced into or moved within protected zones under special requirements, respectively.
- (9) On the basis of information received from Portugal, the Terceira island had already been excluded from the protected zone of Portugal in Annex III to Implementing Regulation (EU) 2019/2072 in respect of *Gonipterus scutellatus* Gyllenhal by Commission Implementing Regulation (EU) 2020/2210 ⁽³⁾, without amending Annex X to Implementing Regulation (EU) 2019/2072. Therefore, it is appropriate to amend the reference to that protected zone in that Annex as well.
- (10) Implementing Regulation (EU) 2019/2072 should therefore be amended accordingly.
- (11) In the interest of clarity, the amendments relating to areas that had been recognised as protected zones pursuant to Implementing Regulation (EU) 2019/2072 until 30 April 2020 should apply retroactively with effect from 1 May 2020.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2019/2072 is amended as follows:

- (1) in Article 13(2), point (b) is replaced by the following:

‘(b) they are not subject to the special requirements of Annex VIII or Annex X to this Regulation or to those provided for by the implementing acts adopted pursuant to Articles 28(1), 30(1) or 49(1) of Regulation (EU) 2016/2031.’;

⁽³⁾ Commission Implementing Regulation (EU) 2020/2210 of 22 December 2020 amending Annexes III, VI, VII, IX, X, XI and XII to Implementing Regulation (EU) 2019/2072 as regards the requirements concerning the protected zone of Northern Ireland and the prohibitions and requirements for the introduction into the Union of plants, plant products and other objects from the United Kingdom (OJ L 438, 28.12.2020, p. 28).

- (2) Annex III is amended in accordance with Part 1 of the Annex to this Regulation;
- (3) Annex IX is amended in accordance with Part 2 of the Annex to this Regulation;
- (4) Annex X is amended in accordance with Part 3 of the Annex to this Regulation.

Article 2

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

However, the following points shall apply from 1 May 2020:

- point (2) of Article 1, except point (2) of Part 1 of the Annex;
- point (3) of Article 1;
- point (4) of Article 1, except point (3) of Part 3 of the Annex.

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

Done at Brussels, 7 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

PART 1

Amendments to Annex III to Implementing Regulation (EU) 2019/2072

The table in Annex III to Implementing Regulation (EU) 2019/2072 is amended as follows:

(1) in section (a) 'Bacteria', the third column 'Protected zones' of point 1 is amended as follows:

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

'(d) Italy (Abruzzo, Apúlia, Basilicata, Calabria, Campania (except the municipalities of Agerola, Gragnano, Lettere, Pimonte and Vico Equense in the province of Naples, Amalfi, Atrani, Conca dei Marini, Corbara, Furore, Maiori, Minori, Positano, Praiano, Ravello, Scala and Tramonti in the province of Salerno), Lazio, Liguria, Lombardy (except the provinces of Milan, Mantua, Sondrio and Varese, and the communes of Bovisio Masciago, Cesano Maderno, Desio, Limbiate, Nova Milanese and Varedo in Monza Brianza Province), Marche (except the communes of Colli al Metauro, Fano, Pesaro and San Costanzo in the province of Pesaro e Urbino), Molise, Sardinia, Sicily (except the municipalities of Cesarò in the province of Messina, Maniace, Bronte, Adrano in the province of Catania and Centuripe, Regalbuto and Troina in the province of Enna), Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and Vescovana in the province of Padova and the communes of Albaredo d'Adige, Angiari, Arcole, Belfiore, Bevilacqua, Bonavigo, Boschi S. Anna, Bovolone, Buttapietra, Caldiero, Casaleone, Castagnaro, Castel d'Azzano, Cerea, Cologna Veneta, Concamarise, Erbè, Gazzo Veronese, Isola della Scala, Isola Rizza, Legnago, Minerbe, Mozzecane, Nogara, Nogarole Rocca, Oppeano, Palù, Povegliano Veronese, Pressana, Ronco all'Adige, Roverchiara, Roveredo di Guà, San Bonifacio, Sanguinetto, San Pietro di Morubbio, San Giovanni Lupatoto, Salizzole, San Martino Buon Albergo, Sommacampagna, Sorgà, Terrazzo, Trevenzuolo, Valeggio sul Mincio, Veronella, Villa Bartolomea, Villafranca di Verona, Vigasio, Zevio, Zimella in the province of Verona));';

(b) points (g) to (k) are replaced by the following:

'(g) Ireland (except Galway city);

(h) Lithuania (except the municipality of Kėdainiai in the region of Kaunas);

(i) Slovenia (except the regions of Gorenjska, Koroška, Maribor and Notranjska, and the communes of Dol pri Ljubljani, Lendava, Litija, Moravče, Renče-Vogrsko, Velika Polana and Žužemberk, and the settlements Fuzina, Gabrovčec, Glogovica, Gorenja vas, Gradiček, Grintovec, Ivančna Gorica, Krka, Krška vas, Male Lese, Malo Črnelo, Malo Globoko, Marinča vas, Mleščevo, Mrzlo Polje, Muljava, Podbukovje, Potok pri Muljavi, Šentvid pri Stični, Škrjanče, Trebnja Gorica, Velike Lese, Veliko Črnelo, Veliko Globoko, Vir pri Stični, Vrhpolje pri Šentvidu, Zagradec and Znojile pri Krki in the commune Ivančna Gorica);

(j) Slovakia (except the county of Dunajská Streda, and the townships of Hronovce and Hronské Kľačany in the Levice County, Dvory nad Žitavou in the Nové Zámky County, Málinec in the Poltár County, Valice, Jesenské and Rimavská Sobota in the Rimavská Sobota County, Hrhov in the Rožňava County, Veľké Ripňany in the Topoľčany County, Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátin in the Trebišov County).';

(2) in section (c) 'Insects and mites', point 19 is replaced by the following:

'19.	<i>Thaumetopoea pityocampa</i> Denis & Schiffermüller	THAUPI	(a) until 30 April 2023: Ireland; (b) United Kingdom (Northern Ireland).'
------	---	--------	--

PART 2

Amendments to Annex IX to Implementing Regulation (EU) 2019/2072

Annex IX to Implementing Regulation (EU) 2019/2072 is amended as follows:

(1) in point 1, the third column 'Protected zones' is amended as follows:

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

'(e) Italy (Abruzzo, Apúlia, Basilicata, Calabria, Campania (except the municipalities of Agerola, Gragnano, Lettere, Pimonte and Vico Equense in the province of Naples, Amalfi, Atrani, Conca dei Marini, Corbara, Furore, Maiori, Minori, Positano, Praiano, Ravello, Scala and Tramonti in the province of Salerno), Lazio, Liguria, Lombardy (except the provinces of Milan, Mantua, Sondrio and Varese, and the communes of Bovisio Masciago, Cesano Maderno, Desio, Limbiate, Nova Milanese and Varedo in Monza Brianza Province), Marche (except the communes of Colli al Metauro, Fano, Pesaro and San Costanzo in the province of Pesaro e Urbino), Molise, Sardinia, Sicily (except the municipalities of Cesarò in the province of Messina, Maniace, Bronte, Adrano in the province of Catania and Centuripe, Regalbuto and Troina in the province of Enna), Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and Vescovana in the province of Padova and the communes of Albaredo d'Adige, Angiari, Arcole, Belfiore, Bevilacqua, Bonavigo, Boschi S. Anna, Bovolone, Buttapietra, Caldiero, Casaleone, Castagnaro, Castel d'Azzano, Cerea, Cologna Veneta, Concamarise, Erbè, Gazzo Veronese, Isola della Scala, Isola Rizza, Legnago, Minerbe, Mozzecane, Nogara, Nogarole Rocca, Oppeano, Palù, Povegliano Veronese, Pressana, Ronco all'Adige, Roverchiara, Roveredo di Guà, San Bonifacio, Sanguinetto, San Pietro di Morubbio, San Giovanni Lupatoto, Salizzole, San Martino Buon Albergo, Sommacampagna, Sorgà, Terrazzo, Trevenzuolo, Valeggio sul Mincio, Veronella, Villa Bartolomea, Villafranca di Verona, Vigasio, Zevio, Zimella in the province of Verona));

(b) points (g) to (i) are replaced by the following:

'(g) Lithuania (except the municipality of Kėdainiai in the region of Kaunas);

(h) Slovenia (except the regions of Gorenjska, Koroška, Maribor and Notranjska, and the communes of Dol pri Ljubljani, Lendava, Litija, Moravče, Renče-Vogrsko, Velika Polana and Žužemberk, and the settlements Fužina, Gabrovčec, Glogovica, Gorenja vas, Gradiček, Grintovec, Ivančna Gorica, Krka, Krška vas, Male Lese, Malo Črnelo, Malo Globoko, Marinča vas, Mleščevo, Mrzlo Polje, Muljava, Podbukovje, Potok pri Muljavi, Šentvid pri Stični, Škranje, Trebnja Gorica, Velike Lese, Veliko Črnelo, Veliko Globoko, Vir pri Stični, Vrhpolje pri Šentvidu, Zagradec and Znojile pri Krki in the commune Ivančna Gorica);

(i) Slovakia (except the county of Dunajská Streda, and the townships of Hronovce and Hronské Kláčany in the Levice County, Dvory nad Žitavou in the Nové Zámky County, Málinec in the Poltár County, Valice, Jesenské and Rimavská Sobota in the Rimavská Sobota County, Hrhov in the Rožňava County, Veľké Ripňany in the Topoľčany County, Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátin in the Trebišov County);

(2) in point 2, the third column 'Protected zones' is amended as follows:

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

'(e) Italy (Abruzzo, Apúlia, Basilicata, Calabria, Campania (except the municipalities of Agerola, Gragnano, Lettere, Pimonte and Vico Equense in the province of Naples, Amalfi, Atrani, Conca dei Marini, Corbara, Furore, Maiori, Minori, Positano, Praiano, Ravello, Scala and Tramonti in the province of Salerno), Lazio, Liguria, Lombardy (except the provinces of Milan, Mantua, Sondrio and Varese, and the communes of Bovisio Masciago, Cesano Maderno, Desio, Limbiate, Nova Milanese and Varedo in Monza Brianza Province), Marche (except the communes of Colli al Metauro, Fano, Pesaro and San Costanzo in the province of Pesaro e Urbino), Molise, Sardinia, Sicily (except the municipalities of Cesarò in the province of Messina, Maniace, Bronte, Adrano in the province of Catania and Centuripe, Regalbuto and Troina in the province of Enna), Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and Vescovana in the province of Padova and the communes of Albaredo d'Adige, Angiari, Arcole, Belfiore, Bevilacqua, Bonavigo, Boschi S. Anna, Bovolone, Buttapietra, Caldiero, Casaleone, Castagnaro, Castel d'Azzano, Cerea, Cologna Veneta, Concamarise, Erbè, Gazzo Veronese, Isola della Scala, Isola Rizza, Legnago, Minerbe, Mozzecane, Nogara, Nogarole Rocca,

Oppeano, Palù, Povegliano Veronese, Pressana, Ronco all'Adige, Roverchiara, Roveredo di Guà, San Bonifacio, Sanguinetto, San Pietro di Morubio, San Giovanni Lupatoto, Salizzole, San Martino Buon Albergo, Sommacampagna, Sorgà, Terrazzo, Trevenzuolo, Valeggio sul Mincio, Veronella, Villa Bartolomea, Villafranca di Verona, Vigasio, Zevio, Zimella in the province of Verona));

(b) points (g) to (i) are replaced by the following:

‘(g) Lithuania (except the municipality of Kėdainiai in the region of Kaunas);

(h) Slovenia (except the regions of Gorenjska, Koroška, Maribor and Notranjska, and the communes of Dol pri Ljubljani, Lendava, Litija, Moravče, Renče-Vogrsko, Velika Polana and Žužemberk, and the settlements Fužina, Gabrovčec, Glogovica, Gorenja vas, Gradiček, Grintovec, Ivančna Gorica, Krka, Krška vas, Male Lese, Malo Črnelo, Malo Globoko, Marinča vas, Mleščevo, Mrzlo Polje, Muljava, Podbukovje, Potok pri Muljavi, Šentvid pri Stični, Škrjanče, Trebnja Gorica, Velike Lese, Veliko Črnelo, Veliko Globoko, Vir pri Stični, Vrhpolje pri Šentvidu, Zagradec and Znojile pri Krki in the commune Ivančna Gorica);

(i) Slovakia (except the county of Dunajská Streda, and the townships of Hronovce and Hronské Kľačany in the Levice County, Dvory nad Žitavou in the Nové Zámky County, Málinec in the Poltár County, Valice, Jesenské and Rimavská Sobota in the Rimavská Sobota County, Hrhov in the Rožňava County, Veľké Ripňany in the Topoľčany County, Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátin in the Trebišov County);’

PART 3

Amendments to Annex X to Implementing Regulation (EU) 2019/2072

Annex X to Implementing Regulation (EU) 2019/2072 is amended as follows:

(1) in point 3, the fourth column ‘Protected zones’ is amended as follows:

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

‘(e) Italy (Abruzzo, Apulia, Basilicata, Calabria, Campania (except the municipalities of Agerola, Gragnano, Lettere, Pimonte and Vico Equense in the province of Naples, Amalfi, Atrani, Conca dei Marini, Corbara, Furore, Maiori, Minori, Positano, Praiano, Ravello, Scala and Tramonti in the province of Salerno), Lazio, Liguria, Lombardy (except the provinces of Milan, Mantua, Sondrio and Varese, and the communes of Bovisio Masciago, Cesano Maderno, Desio, Limbiate, Nova Milanese and Varedo in Monza Brianza Province), Marche (except the communes of Colli al Metauro, Fano, Pesaro and San Costanzo in the province of Pesaro e Urbino), Molise, Sardinia, Sicily (except the municipalities of Cesarò in the province of Messina, Maniace, Bronte, Adrano in the province of Catania and Centuripe, Regalbuto and Troina in the province of Enna), Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and Vescovana in the province of Padova and the communes of Albaredo d'Adige, Angiari, Arcole, Belfiore, Bevilacqua, Bonavigo, Boschi S. Anna, Bovolone, Buttapietra, Caldiero, Casaleone, Castagnaro, Castel d'Azzano, Cerea, Cologna Veneta, Concarnarise, Erbe, Gazzo Veronese, Isola della Scala, Isola Rizza, Legnago, Minerbe, Mozzecane, Nogara, Nogarole Rocca, Oppeano, Palù, Povegliano Veronese, Pressana, Ronco all'Adige, Roverchiara, Roveredo di Guà, San Bonifacio, Sanguinetto, San Pietro di Morubio, San Giovanni Lupatoto, Salizzole, San Martino Buon Albergo, Sommacampagna, Sorgà, Terrazzo, Trevenzuolo, Valeggio sul Mincio, Veronella, Villa Bartolomea, Villafranca di Verona, Vigasio, Zevio, Zimella in the province of Verona));

(b) points (g) to (i) are replaced by the following:

‘(g) Lithuania (except the municipality of Kėdainiai in the region of Kaunas)

(h) Slovenia (except the regions of Gorenjska, Koroška, Maribor and Notranjska, and the communes of Dol pri Ljubljani, Lendava, Litija, Moravče, Renče-Vogrsko, Velika Polana and Žužemberk, and the settlements Fužina, Gabrovčec, Glogovica, Gorenja vas, Gradiček, Grintovec, Ivančna Gorica, Krka, Krška vas, Male Lese, Malo

- Črnelo, Malo Globoko, Marinča vas, Mleščevo, Mrzlo Polje, Muljava, Podbukovje, Potok pri Muljavi, Šentvid pri Stični, Škrjanče, Trebnja Gorica, Velike Lese, Veliko Črnelo, Veliko Globoko, Vir pri Stični, Vrhpolje pri Šentvidu, Zagradec and Znojile pri Krki in the commune Ivančna Gorica);
- (i) Slovakia (except the county of Dunajská Streda, and the townships of Hronovce and Hronské Kľačany in the Levice County, Dvory nad Žitavou in the Nové Zámky County, Málinec in the Poltár County, Valice, Jesenské and Rimavská Sobota in the Rimavská Sobota County, Hrhov in the Rožňava County, Veľké Ripňany in the Topoľčany County, Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátin in the Trebišov County);
- (2) in point 9, the fourth column 'Protected zones' is amended as follows:
- (a) point (e) is replaced by the following:
- '(e) Italy (Abruzzo, Apúlia, Basilicata, Calabria, Campania (except the municipalities of Agerola, Gragnano, Lettere, Pimonte and Vico Equense in the province of Naples, Amalfi, Atrani, Conca dei Marini, Corbara, Furore, Maiori, Minori, Positano, Praiano, Ravello, Scala and Tramonti in the province of Salerno), Lazio, Liguria, Lombardy (except the provinces of Milan, Mantua, Sondrio and Varese, and the communes of Bovisio Masciago, Cesano Maderno, Desio, Limbiate, Nova Milanese and Varedo in Monza Brianza Province), Marche (except the communes of Colli al Metauro, Fano, Pesaro and San Costanzo in the province of Pesaro e Urbino), Molise, Sardinia, Sicily (except the municipalities of Cesarò in the province of Messina, Maniace, Bronte, Adrano in the province of Catania and Centuripe, Regalbuto and Troina in the province of Enna), Tuscany, Umbria, Valle d'Aosta, Veneto (except the provinces of Rovigo and Venice, the communes Barbona, Boara Pisani, Castelbaldo, Masi, Piacenza d'Adige, S. Urbano and Vescovana in the province of Padova and the communes of Albaredo d'Adige, Angiari, Arcole, Belfiore, Bevilacqua, Bonavigo, Boschi S. Anna, Bovolone, Buttapietra, Caldiero, Casaleone, Castagnaro, Castel d'Azzano, Cerea, Cologna Veneta, Concamarise, Erbè, Gazzo Veronese, Isola della Scala, Isola Rizza, Legnago, Minerbe, Mozzecane, Nogara, Nogarole Rocca, Oppeano, Palù, Povegliano Veronese, Pressana, Ronco all'Adige, Roverchiara, Roveredo di Guà, San Bonifacio, Sanguinetto, San Pietro di Morubbio, San Giovanni Lupatoto, Salizzole, San Martino Buon Albergo, Sommacampagna, Sorgà, Terrazzo, Trevenzuolo, Valeggio sul Mincio, Veronella, Villa Bartolomea, Villafranca di Verona, Vigasio, Zevio, Zimella in the province of Verona));
- (b) points (g) to (i) are replaced by the following:
- '(g) Lithuania (except the municipality of Kėdainiai in the region of Kaunas)
- (h) Slovenia (except the regions of Gorenjska, Koroška, Maribor and Notranjska, and the communes of Dol pri Ljubljani, Lendava, Litija, Moravče, Renče-Vogrsko, Velika Polana and Žužemberk, and the settlements Fužina, Gabrovčec, Glogovica, Gorenja vas, Gradiček, Grintovec, Ivančna Gorica, Krka, Krška vas, Male Lese, Malo Črnelo, Malo Globoko, Marinča vas, Mleščevo, Mrzlo Polje, Muljava, Podbukovje, Potok pri Muljavi, Šentvid pri Stični, Škrjanče, Trebnja Gorica, Velike Lese, Veliko Črnelo, Veliko Globoko, Vir pri Stični, Vrhpolje pri Šentvidu, Zagradec and Znojile pri Krki in the commune Ivančna Gorica);
- (i) Slovakia (except the county of Dunajská Streda, and the townships of Hronovce and Hronské Kľačany in the Levice County, Dvory nad Žitavou in the Nové Zámky County, Málinec in the Poltár County, Valice, Jesenské and Rimavská Sobota in the Rimavská Sobota County, Hrhov in the Rožňava County, Veľké Ripňany in the Topoľčany County, Kazimír, Luhyňa, Malý Horeš, Svätuš and Zátin in the Trebišov County);
- (3) in point 16, the text in the fourth column 'Protected zones' is replaced by the following:
- (a) Ireland
- (b) United Kingdom (Northern Ireland);
- (4) in point 19, the text in the fourth column 'Protected zones' is replaced by the following:
- (a) Greece
- (b) Portugal (Azores, except the Terceira island);

COMMISSION IMPLEMENTING REGULATION (EU) 2021/760**of 7 May 2021****amending Implementing Regulations (EU) 2020/761 and (EU) 2020/1988 as regards the management system of some tariff quotas with licences and repealing Implementing Regulation (EU) 2020/991**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 187 and Article 223(3) thereof,

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ⁽²⁾, and in particular Article 66(4) thereof,

Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 ⁽³⁾, and in particular Article 9, first paragraph, points (a) to (d), and Article 16(1), first subparagraph, point (a), thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/761 ⁽⁴⁾ lays down the rules for the management of import and export tariff quotas for agricultural products managed by a system of import and export licences and replaces and repeals a certain number of acts that have opened these quotas and provides for specific rules.
- (2) In order to clarify precisely by when Member States need to notify the quantities covered by licences and the information related to the Licence Operator Registration and Identification electronic system ('LORI electronic system') referred to in Article 13 of Commission Delegated Regulation (EU) 2020/760 ⁽⁵⁾, certificates of authenticity and IMA1 certificates, Articles 16, 17 and 61 of Implementing Regulation (EU) 2020/761 should be amended.
- (3) The rules on the validity of IMA 1 certificates for dairy products need to be amended and aligned to the general rules on the period of validity of import licences. Therefore, the last sentence of Article 53(6) of Implementing Regulation (EU) 2020/761 should be deleted.
- (4) In case operators apply for export licences electronically they should also be allowed to submit in the same way the declaration of eligibility of United States importers accompanying applications for export licences under cheese quotas opened by the United States. Therefore, Article 59 of Implementing Regulation (EU) 2020/761 should be amended.
- (5) Pursuant to Article 61(2) of Implementing Regulation (EU) 2020/761, Member States have the duty to notify to the Commission all data referring to operators who lodged applications for export under the cheese quotas opened by the United States, including their EORI number. Since not all operators are required to have such a number, Member States should notify this number only in case of operators having it. Therefore, that Article needs to be amended.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 347, 20.12.2013, p. 549.

⁽³⁾ OJ L 150, 20.5.2014, p. 1.

⁽⁴⁾ Commission Implementing Regulation (EU) 2020/761 of 17 December 2019 laying down rules for the application of Regulations (EU) No 1306/2013, (EU) No 1308/2013 and (EU) No 510/2014 of the European Parliament and of the Council as regards the management system of tariff quotas with licences (OJ L 185, 12.6.2020, p. 24).

⁽⁵⁾ Commission Delegated Regulation (EU) 2020/760 of 17 December 2019 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the rules for the administration of import and export tariff quotas subject to licences and supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards the lodging of securities in the administration of tariff quotas (OJ L 185, 12.6.2020, p. 1).

- (6) Pursuant to Articles 71(3), and 72(2), of Implementing Regulation (EU) 2020/761, and by derogation from Article 6(1) and (2) of that Regulation, operators applying for export tariff quotas managed by third countries and subject to specific Union rules, and for import tariff quotas managed with documents issued by the exporting countries, can submit more than one application for licences per month, any day. In order to ensure consistency of this management method, the derogation from Article 6 of that Regulation should refer to the whole Article and not only to its paragraphs 1 and 2. Moreover, Article 72(4) of that Regulation should be corrected by introducing a specific reference to IMA 1 certificates.
- (7) For the sake of clarity, it is appropriate to harmonise the rules concerning the filling of Sections 8 and 24 of applications for import licences and of licences, with regard to the indication of the country of origin of goods. Therefore, Articles 22 and 29 of Implementing Regulation (EU) 2020/761, as well as the relevant boxes of tariff quotas in Annexes II to XII to that Regulation should be amended.
- (8) Commission Implementing Regulation (EU) 2020/991 ⁽⁶⁾ opens three tariff quotas for rice originating in Vietnam. In view to harmonise the management of these tariff quotas with the rules laid down in Implementing Regulation (EU) 2020/761, the tables and the rules governing those three tariff quotas should be integrated into Implementing Regulation (EU) 2020/761 and Implementing Regulation (EU) 2020/991 should be repealed. Therefore, Articles 27 and 29 of Implementing Regulation (EU) 2020/761 should be amended, and a new Article 29a should be integrated into that Regulation.
- (9) The table concerning tariff quota with order number 09.4450 set out in Annex VIII to Implementing Regulation (EU) 2020/761 should be updated with the new beef classification and the new name of the authority competent for issuing Certificates of authenticity communicated by Argentina.
- (10) To avoid any misunderstanding concerning the maximum age of bovine animals whose carcasses are eligible under tariff quota with order number 09.4002 set out in Annex VIII to Implementing Regulation (EU) 2020/761, the relevant table of that Annex should be amended.
- (11) In order to exclude tenderloins from the products eligible under tariff quotas with order numbers 09.4038 and 09.4170 set out in Annex X to Implementing Regulation (EU) 2020/761, the relevant tables of that Annex should be amended.
- (12) Reference to Article 61 of Regulation (EU) No 952/2013 of the European Parliament and of the Council ⁽⁷⁾ in the box 'Proof of origin for release into free circulation' of the tables of several tariff quotas is not necessary, and it might be misinterpreted. To avoid any misinterpretation and consequent issues to trade operators, such reference should be deleted. In the same sense, Article 4(5) of Commission Implementing Regulation (EU) 2020/1988 ⁽⁸⁾ should be amended to clarify the scope of its reference to Article 61 of Regulation (EU) No 952/2013. Moreover, the reference to certificates of authenticity in Article 4(4) of Implementing Regulation (EU) 2020/1988 should be extended to all documents mentioned in Chapter II and Annex II to that Regulation.
- (13) In order to simplify the management of tariff quotas governed by Implementing Regulation (EU) 2020/1988 certain parent-quotas for butter and veal should be deleted and the relevant sub-quotas should be managed as tariff quotas.
- (14) Following a mistake in integrating Council Regulation (EC) No 1095/96 ⁽⁹⁾ into Implementing Regulation (EU) 2020/1988, the table of tariff quota under order number 09.0141 should be integrated with all the other order numbers that govern the products listed in its product description, with effect on the ongoing tariff quota period.

⁽⁶⁾ Commission Implementing Regulation (EU) 2020/991 of 13 May 2020 opening and providing for the administration of import tariff quotas for rice originating in the Socialist Republic of Vietnam (OJ L 221, 10.7.2020, p. 64).

⁽⁷⁾ Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

⁽⁸⁾ Commission Implementing Regulation (EU) 2020/1988 of 11 November 2020 laying down rules for the application of Regulations (EU) No 1308/2013 and No 510/2014 of the European Parliament and of the Council as regards the administration of import tariff quotas in accordance with the 'first come first served' principle (OJ L 422, 14.12.2020, p. 4).

⁽⁹⁾ Council Regulation (EC) No 1095/96 of 18 June 1996 on the implementation of the concessions set out in Schedule CXL drawn up in the wake of the conclusion of the GATT XXIV.6 negotiations (OJ L 146, 20.6.1996, p. 1).

- (15) Implementing Regulations (EU) 2020/761 and (EU) 2020/1988 should therefore be amended accordingly.
- (16) In order to ensure the timely application of the amendments when operators will submit licence applications for tariff quotas with periods starting in July 2021, this Regulation should enter into force as a matter of urgency on the day following that of its publication in the *Official Journal of the European Union*. Amendments to tariff quotas managed with licences should apply as from the first licence application period following the entry into force of this Regulation, with the exception of those modifying the requirements of proof of origin for release into free circulation for tariff quotas with order numbers 09.4123, 09.4125, 09.4112, 09.4116, 09.4117, 09.4118, 09.4119, 09.4130 and 09.4154, which should apply from the beginning of the ongoing tariff quota periods. Amendments to tariff quotas managed on a 'first come first served' principle should apply to the ongoing tariff quota periods as from their beginning. Amendments concerning the integration of Implementing Regulation (EU) 2020/991 into Implementing Regulation (EU) 2020/761 should apply as of the next tariff quota period starting on 1 January 2022.
- (17) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2020/761

Implementing Regulation (EU) 2020/761 is amended as follows:

- (1) Article 16 is amended as follows:
- (a) paragraph 2 is amended as follows:
 - (i) in point (a), the word 'before' is replaced by 'at the latest on';
 - (ii) in point (b), the word 'before' is replaced by 'at the latest on';
 - (b) paragraph 3, first subparagraph, is amended as follows:
 - (i) in point (a), the word 'before' is replaced by 'at the latest on';
 - (ii) in point (b), the word 'before' is replaced by 'at the latest on';
 - (iii) in point (c), the word 'before' is replaced by 'at the latest on';
- (2) in Article 17, paragraph 5 is amended as follows:
- (a) in point (a), the word 'before' is replaced by 'at the latest on';
 - (b) in point (b), the word 'before' is replaced by 'at the latest on';
- (3) Article 22 is replaced by the following:

'Article 22

Application and licence content

The import licence application and the licence shall in all cases mention in Section 24 one of the entries listed in Annex XIV.;

- (4) Article 27 is amended as follows:
- (a) in the fourth paragraph the words 'and 09.4168' are replaced by ', 09.4168, 09.4729, 09.4730 and 09.4731';
 - (b) the following sixth paragraph is added:

'For tariff quotas under order numbers 09.4729, 09.4730 and 09.4731 Member States shall notify, in accordance with Article 16, the Commission of quantities in product weight and the Commission shall transform these quantities into the weight equivalent specified in Annex III.;

(5) Article 29 is amended as follows:

(a) the words 'and 09.4168' are replaced by ', 09.4168, 09.4119, 09.4130 and 09.4154';

(b) the following paragraph is added:

'By way of derogation from Article 6(5), import licence applications for tariff quotas 09.4729, 09.4730 and 09.4731 shall refer to a single order number and a single CN code. The description of the products and their CN code shall be referred to in Sections 15 and 16, respectively, of the licence application.';

(6) The following Article 29a is inserted:

'Article 29a

Authenticity certificate

1. The authenticity certificate, issued by a competent body of Vietnam listed in Annex III, stating that the rice belongs to one of the specific varieties of fragrant rice set out for tariff quota with order number 09.4731 shall be drawn up on a form in accordance with the specimen laid down in Annex XIV.2 RICE – Part D. Origin Vietnam. The forms shall be printed and completed in English.

2. Each authenticity certificate shall bear an individual serial number allocated by the issuing authorities in the top right-hand box. The copies shall bear the same number as the original.

3. The authenticity certificate shall be valid for 120 days from the date of issue. It shall be valid only if the boxes are duly completed and it is signed. The authenticity certificates shall be considered to have been duly signed if they state the date and place of issue and if they bear the stamp of the issuing authority and the signature of the person or persons empowered to sign them.

4. The authenticity certificate shall be submitted to the customs authorities in order to verify the existence of the necessary conditions to benefit from the tariff quota with order number 09.4731. The competent body of Vietnam listed in Annex III, shall provide the Commission with any relevant information, which may assist in verifying the information contained on the certificates of authenticity, in particular specimens of the stamps it has used.';

(7) in Article 53, paragraph 6 is replaced by the following:

'6. A duly authenticated copy of the IMA 1 certificate shall be presented, along with the corresponding import licence and the products to which they relate, to the customs authorities of the importing Member State at the same time when the declaration of release for free circulation in the Union is lodged.';

(8) in Article 59, paragraph 8 is replaced by the following:

'8. Applications for export licences shall be accompanied by a declaration from the designated United States importer stating its eligibility for import under the United States rules on dairy tariff-rate quota import licensing laid down in part 6 of subtitle A of Title 7 of the Code of Federal Regulations. In case of electronic application, an electronic copy of this declaration may be submitted.';

(9) Article 61 is amended as follows:

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

'(a) a list of applicants, stating their name, address, and EORI number if applicable';

(b) in paragraph 3, the word 'Before' is replaced by the words 'At the latest on';

(10) in Article 71, paragraph 3 is replaced by the following:

'3. By way of derogation from Article 6, operators may lodge more than one licence application per month, and licence applications may be submitted any day, taking account of Article 3 of Implementing Regulation (EU) 2016/1239.';

(11) Article 72 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. By way of derogation from Article 6, operators may lodge more than one licence application per month and licence applications may be submitted at any day, taking account of Article 3 of Implementing Regulation (EU) 2016/1239.';

(b) paragraph 4 is replaced by the following:

‘4. The licence issuing authority shall verify that information on the certificate of authenticity and on the IMA 1 certificate corresponds to the information it received from the Commission. If that is the case and unless instructed otherwise by the Commission, the licence issuing authority shall issue import licences without delay, no later than six calendar days after receiving the application submitted with a certificate of authenticity or IMA 1 certificate.’;

(12) Annexes I, II, III, IV, VI, VII, VIII, IX, X, XI, XII and XIV.2 RICE are amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Implementing Regulation (EU) 2020/1988

Implementing Regulation (EU) 2020/1988 is amended as follows:

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

‘2. Article 53(2), points (b) and (c), and Article 53(3) of Implementing Regulation (EU) 2015/2447 shall not apply to tariff quotas and sub-tariff quotas under order numbers 09.0138, 09.0139, 09.0140, 09.0141, 09.0165, 09.0166, 09.0167, 09.0168, 09.0169, 09.0142, 09.0143, 09.0161, 09.0162, 09.0163, 09.0164, 09.0146, 09.0147, 09.0148, 09.0149, 09.0150, 09.0151, 09.0152, 09.0159, 09.0160, 09.0154, 09.0155, 09.0156, 09.0157 and 09.0158.’;

(2) Article 4 is amended as follows:

(a) paragraph 4 is replaced by the following:

‘4. Where additional documents are required, they shall comply with the requirements laid down in Chapter II and Annex II to this Regulation.’;

(b) paragraph 5 is replaced by the following:

‘5. If necessary, customs authorities may additionally require the declarant or importer to prove the origin of the products in accordance with Article 61 of Regulation (EU) No 952/2013 or relevant provisions of the trade arrangement concerned.’;

(3) Article 13 is amended as follows:

(a) the heading is replaced by the following:

‘Article 13

Tariff quotas under order numbers 09.0141, 09.0165, 09.0166, 09.0167, 09.0168 and 09.0169’;

(b) paragraph 1 is replaced by the following:

‘1. Import within the tariff quotas under order numbers 09.0141, 09.0165, 09.0166, 09.0167, 09.0168 and 09.0169 shall be subject to the presentation of a certificate of origin.’;

(4) Article 17 is replaced by the following:

‘Article 17

Management of tariff quotas under order numbers 09.0161, 09.0162, 09.0163 and 09.0164

Tariff quotas under order numbers 09.0161 and 09.0163 shall be used to apply for CN code ex 0202 20 30; tariff quotas under order numbers 09.0162 and 09.0164 shall be used to apply for CN codes ex 0202 30 10, ex 0202 30 50, ex 0202 30 90 and ex 0206 29 91.’;

(5) Article 18 is amended as follows:

(a) the heading is replaced by the following:

'Article 18

Definitions for tariff quotas under order numbers 09.0161, 09.0162, 09.0163 and 09.0164;

(b) in paragraph 1, the order number '09.0144' is deleted;

(c) in paragraph 2, the order number '09.0145' is deleted;

(6) Article 19 is amended as follows:

(a) the heading is replaced by the following:

'Article 19

Specific provisions for tariff quotas under order numbers 09.0161, 09.0162, 09.0163 and 09.0164;

(b) in paragraph 3, the words '09.0144 and 09.0145 and sub-tariff quotas under order numbers' are deleted;

(7) Article 29 is replaced by the following:

'Article 29

Tariff quotas under order numbers 09.0159 and 09.0160

Tariff quota 09.0159 shall be used to apply for CN code 0405 10; tariff quota 09.0160 shall be used to apply for CN code 0405 90.;

(8) Annexes I and II are amended in accordance with Annex II to this Regulation.

Article 3

Repeal

Implementing Regulation (EU) 2020/991 is repealed with effect from 1 January 2022.

Article 4

Entry into force and application

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

Article 1 shall apply as from the first licence application period following the entry into force of this Regulation.

However:

(a) points (2)(d) and (3)(e) of Annex I shall apply from the beginning of the ongoing tariff quota periods;

(b) Article 1, point (4), point (5)(b) and point (6), and point (1), point (3)(f) and point (12) of Annex I shall apply from 1 January 2022.

Article 2 shall apply from the beginning of the ongoing tariff quota periods.

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

Done at Brussels, 7 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annexes I, II, III, IV, VI, VII, VIII, IX, X, XI, XII and XIV.2 RICE to Implementing Regulation (EU) 2020/761 are amended as follows:

(1) in Annex I, below the row related to tariff rate quota 09.4168, the following rows are inserted:

‘09.4729	Rice	Import	EU: simultaneous examination	No	Yes		No
09.4730	Rice	Import	EU: simultaneous examination	No	Yes		No
09.4731	Rice	Import	EU: simultaneous examination	No	Yes		No’

(2) Annex II is amended as follows:

(a) the box ‘Specific entries to be made on the licence application and on the licence’ of the table referring to tariff quota with order number 09.4125 is replaced by the following:

‘Specific entries to be made on the licence application and on the licence’	Licences shall contain in Section 24 the statement “Not to be used for products originating in the United States of America, Canada and the United Kingdom”
--	---

(b) the box ‘Specific entries to be made on the licence application and on the licence’ of the tables referring to tariff quotas with order numbers 09.4131 and 09.4133 is replaced by the following:

‘Specific entries to be made on the licence application and on the licence’	Licences shall contain in Section 24 the statement “Not to be used for products originating in the United Kingdom”
--	--

(c) the box ‘Specific entries to be made on the licence application and on the licence’ of the tables referring to tariff quotas with order numbers 09.4120, 09.4121 and 09.4122 is replaced by the following:

‘Specific entries to be made on the licence application and on the licence’	Licences shall contain in Section 24 the statement “Not to be used for products originating in the United Kingdom”. Section 24 of the licence application shall indicate one of the entries listed in Annex XIV.1 to this Regulation’
--	--

(d) the box ‘Proof of origin for release into free circulation’ of the tables referring to tariff quotas with order numbers 09.4123 and 09.4125 is replaced by the following:

‘Proof of origin for release into free circulation’	No’
--	-----

(3) Annex III is amended as follows:

- (a) the box 'Specific entries to be made on the licence application and on the licence' of the table referring to TRQ with order number 09.4119 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in India, Pakistan, Thailand, the United States and the United Kingdom"
--	---

- (b) the box 'Specific entries to be made on the licence application and on the licence' of the table referring to TRQ with order number 09.4130 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in Australia, Thailand, the United States and the United Kingdom"
--	---

- (c) the box 'Specific entries to be made on the licence application and on the licence' of the tables referring to TRQs with order numbers 09.4138, 09.4148, 09.4166 and 09.4168 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in the United Kingdom"
--	--

- (d) the box 'Specific entries to be made on the licence application and on the licence' of the table referring to TRQ with order number 09.4154, is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in Australia, Guyana, Thailand, the United States and the United Kingdom"
--	---

- (e) the box 'Proof of origin for release into free circulation' of the tables referring to TRQs with order numbers 09.4112, 09.4116, 09.4117, 09.4118, 09.4119, 09.4130 and 09.4154 is replaced by the following:

'Proof of origin for release into free circulation'	No'
--	-----

- (f) the following tables are added:

'Order number'	09.4729
International agreement or other act	Council Decision (EU) 2020/753 of 30 March 2020 on the conclusion of the Free Trade Agreement between the European Union and the Socialist Republic of Viet Nam (OJ L 186, 12.6.2020, p. 1).
Tariff quota period	1 January to 31 December
Tariff quota sub-periods	1 January to 31 March 1 April to 30 June 1 July to 30 September 1 October to 31 December

Licence application	In accordance with Articles 6, 7, 8 and 29 of this Regulation
Product description	Husked rice [expressed in husked rice equivalent]
Origin	Vietnam
Proof of origin at licence application. If yes, body authorised to issue it	No
Proof of origin for release into free circulation	Yes. A proof of origin as defined by Article 15(2) of Protocol 1 to the Free Trade Agreement between the European Union and the Socialist Republic of Viet Nam shall be presented for the release into free circulation.
Quantity in kilograms	20 000 000 kg [expressed in husked rice equivalent], divided as follows: 10 000 000 kg for sub-period 1 January to 31 March 5 000 000 kg for sub-period 1 April to 30 June 5 000 000 kg for sub-period 1 July to 30 September 0 kg for sub-period 1 October to 31 December
CN codes	1006 10 30 1006 10 50 1006 10 71 1006 10 79 1006 20 11 1006 20 13 1006 20 15 1006 20 17 1006 20 92 1006 20 94 1006 20 96 1006 20 98
In-quota customs duty	EUR 0
Proof of trade	Yes, 25 tonnes
Security for import licence	EUR 30 per 1 000 kg
Specific entries to be made on the licence application and on the licence	Section 8 of the import licence application and of the import licence shall contain the name "Viet Nam" or "Viet-Nam" or "Vietnam" and the "Yes" box shall be marked with a cross.
Period of validity of a licence	In accordance with Article 13 of this Regulation
Transferability of licence	Yes
Reference quantity	No
Operator registered in LORI database	No
Specific conditions	Conversion rates between paddy rice, husked rice, semi-milled rice and milled rice referred to in Article 1 of Commission Regulation (EC) No 1312/2008 shall apply

Order number	09.4730
International agreement or other act	Council Decision (EU) 2020/753 of 30 March 2020 on the conclusion of the Free Trade Agreement between the European Union and the Socialist Republic of Viet Nam (OJ L 186, 12.6.2020, p. 1).
Tariff quota period	1 January to 31 December
Tariff quota sub-periods	1 January to 31 March 1 April to 30 June 1 July to 30 September 1 October to 31 December
Licence application	In accordance with Articles 6, 7, 8 and 29 of this Regulation
Product description	Milled rice [expressed in milled rice equivalent]
Origin	Vietnam
Proof of origin at licence application. If yes, body authorised to issue it	No
Proof of origin for release into free circulation	Yes. A proof of origin as defined by Article 15(2) of Protocol 1 to the Free Trade Agreement between the European Union and the Socialist Republic of Viet Nam shall be presented for the release into free circulation.
Quantity in kilograms	30 000 000 kg [expressed in milled rice equivalent], divided as follows: 15 000 000 kg for sub-period 1 January to 31 March 7 500 000 kg for sub-period 1 April to 30 June 7 500 000 kg for sub-period 1 July to 30 September 0 kg for sub-period 1 October to 31 December
CN codes	1006 30 21 1006 30 23 1006 30 25 1006 30 27 1006 30 42 1006 30 44 1006 30 46 1006 30 48 1006 30 61 1006 30 63 1006 30 65 1006 30 67 1006 30 92 1006 30 94 1006 30 96 1006 30 98
In-quota customs duty	EUR 0
Proof of trade	Yes. 25 tonnes
Security for import licence	EUR 30 per 1 000 kg
Specific entries to be made on the licence application and on the licence	Section 8 of the import licence application and of the import licence shall contain the name "Viet Nam" or "Viet-Nam" or "Vietnam" and the "Yes" box shall be marked with a cross.

Period of validity of a licence	In accordance with Article 13 of this Regulation
Transferability of licence	Yes
Reference quantity	No
Operator registered in LORI database	No
Specific conditions	Conversion rates between paddy rice, husked rice, semi-milled rice and milled rice referred to in Article 1 of Commission Regulation (EC) No 1312/2008 shall apply
Order number	09.4731
International agreement or other act	Council Decision (EU) 2020/753 of 30 March 2020 on the conclusion of the Free Trade Agreement between the European Union and the Socialist Republic of Viet Nam (OJ L 186, 12.6.2020, p. 1).
Tariff quota period	1 January to 31 December
Tariff quota sub-periods	1 January to 31 March 1 April to 30 June 1 July to 30 September 1 October to 31 December
Licence application	In accordance with Articles 6, 7, 8 and 29 of this Regulation
Product description	Milled rice [expressed in milled rice equivalent] following varieties of fragrant rice: Jasmine 85 ST 5 ST 20 Nang Hoa 9 (NàngHoa 9) VD 20 RVT OM 4900 OM 5451 Tai nguyen Cho Dao (Tàinguyên Cho Đào)
Origin	Vietnam
Proof of origin at licence application. If yes, body authorised to issue it	No
Proof of origin for release into free circulation	Yes. A proof of origin as defined by Article 15(2) of Protocol 1 to the Free Trade Agreement between the European Union and the Socialist Republic of Viet Nam shall be presented for the release into free circulation. Certificate of Authenticity (CA) the template of which is set out in Annex XIV.2 RICE Part D: Origin Vietnam, Certificate of Authenticity to this Regulation. Issuing authority: Ministry of Agriculture and Rural Development of Viet Nam

Quantity in kilograms	30 000 000 kg [expressed in milled rice equivalent], divided as follows: 15 000 000 kg for sub-period 1 January to 31 March 7 500 000 kg for sub-period 1 April to 30 June 7 500 000 kg for sub-period 1 July to 30 September 0 kg for sub-period 1 October to 31 December
CN codes	1006 10 30 1006 10 50 1006 10 71 1006 10 79 1006 20 11 1006 20 13 1006 20 15 1006 20 17 1006 20 92 1006 20 94 1006 20 96 1006 20 98 1006 30 21 1006 30 23 1006 30 25 1006 30 27 1006 30 42 1006 30 44 1006 30 46 1006 30 48 1006 30 61 1006 30 63 1006 30 65 1006 30 67 1006 30 92 1006 30 94 1006 30 96 1006 30 98
In-quota customs duty	EUR 0
Proof of trade	Yes. 25 tonnes
Security for import licence	EUR 30 per 1 000 kg
Specific entries to be made on the licence application and on the licence	Section 8 of the import licence application and of the import licence shall contain the name "Viet Nam" or "Viet-Nam" or "Vietnam" and the "Yes" box shall be marked with a cross.
Period of validity of a licence	In accordance with Article 13 of this Regulation
Transferability of licence	Yes
Reference quantity	No
Operator registered in LORI database	No
Specific conditions	Conversion rates between paddy rice, husked rice, semi-milled rice and milled rice referred to in Article 1 of Commission Regulation (EC) No 1312/2008 shall apply

- (4) in Annex IV, the box 'Specific entries to be made on the licence application and on the licence' of the table referring to tariff quota with order number 09.4320 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Section 20 shall indicate 'Sugar' intended for refining' and the text as set out in Annex XIV.3 Part A to this Regulation Licences shall contain in Section 24 the statement "Not to be used for products originating in the United Kingdom"'
--	--

- (5) in Annex VI, the box 'Specific entries to be made on the licence application and on the licence' of the table referring to tariff quota with order number 09.4287 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in China, Argentina and the United Kingdom"
--	---

- (6) in Annex VII, the box 'Specific entries to be made on the licence application and on the licence' of the table referring to tariff quota with order number 09.4286 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in China and the United Kingdom"
--	--

- (7) Annex VIII is amended as follows:

- (a) the box 'Specific entries to be made on the licence application and on the licence' of the table referring to tariff quota with order number 09.4003 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in the United Kingdom"
--	--

- (b) the boxes 'Product description' and 'Proof of origin at licence application.' of the table referring to tariff quota with order number 09.4450 are replaced by the following:

'Product Description'	High quality boneless beef meeting the following definition: "Selected beef cuts obtained from steers, young steers or heifers having been exclusively fed through pasture grazing since their weaning. The steer and heavy young steer carcasses shall be classified as 'A', 'B', or 'C'. The light young steer and heifer carcasses shall be classified as 'A' or 'B' according to the official carcass classification system established by the competent authority of the Argentine Republic."
'Proof of origin at licence application. If yes, body authorised to issue it'	Yes. Certificate of Authenticity (CA), the template of which is set out in Annex XIV to this Regulation Issuing authority: Ministerio de Agricultura, Ganadería y Pesca.'

- (c) the box 'Product description' of the table referring to tariff quota with order number 09.4002 is replaced by the following:

'Product Description'	High quality fresh, chilled or frozen meat of bovine animals meeting the following definition: "Carcasses or any cuts obtained from bovine animals less than 30 months of age which have been fed for 100 days or more on nutritionally balanced, high-energy-content rations containing not less than 70 % grain and comprising at least 20 pounds total feed per day. Beef graded 'choice' or 'prime' according to USDA (United States Department of Agriculture) standards automatically meets the above definition. Meat graded 'Canada A', 'Canada AA', 'Canada AAA', 'Canada Choice' and 'Canada Prime', 'A1', 'A2', 'A3' and 'A4', according to the Canadian Food Inspection Agency – Government of Canada, corresponds to this definition".
------------------------------	---

- (8) in Annex IX, the box 'Specific entries to be made on the licence application and on the licence' of the table referring to tariff quota with order number 09.4595 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement 'Not to be used for products originating in the United Kingdom'
--	--

- (9) Annex X is amended as follows:

- (a) the box 'Specific entries to be made on the licence application and on the licence' of the table referring to tariff quota with order number 09.4038, is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement 'Not to be used for products originating in the United Kingdom'
--	--

- (b) the box 'Product description' of the table referring to tariff quotas with order numbers 09.4038 and 09.4170' is replaced by the following:

'Product Description'	Boned loins and hams, fresh, chilled or frozen which shall include: — "Boneless loins": loins and cuts thereof, without tenderloin, with or without subcutaneous fat or rind — ham and cuts of ham'
------------------------------	---

- (10) in Annex XI, the box 'Specific entries to be made on the licence application and on the licence' of the tables referring to tariff quotas with order numbers 09.4401 and 09.4402 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in the United Kingdom"
--	--

(11) Annex XII is amended as follows:

- (a) the box 'Specific entries to be made on the licence application and on the licence' of the tables referring to tariff quotas with order numbers 09.4067, 09.4068, 09.4069, 09.4070 and 09.4422 is replaced by the following:

'Specific entries to be made on the licence application and on the licence'	Licences shall contain in Section 24 the statement "Not to be used for products originating in the United Kingdom"
--	--

- (b) the boxes 'Proof of origin at licence application' and 'Proof of origin for release into free circulation' of the tables referring to tariff quotas with order numbers 09.4410, 09.4411 and 09.4420 are replaced by the following:

'Proof of origin at licence application. If yes, body authorised to issue it'	No.
'Proof of origin for release into free circulation'	Yes. In accordance with Articles 57, 58 and 59 of Regulation (EU) 2015/2447'

(12) in Annex XIV.2 RICE, the following Part D is added:

'PART D. Origin Vietnam'

Certificate of Authenticity

1 Exporter (Name and full address)	CERTIFICATE OF AUTHENTICITY for export to the European Union No ORIGINAL issued by (Name and full address of issuing body)
2 Consignee (Name and full address)	
6 Description of goods	3 country and place of cultivation
	4 country of destination in EU
	5 Packing 5 kg or less (number of packings)
	7 Packing between 5 and 20 kg (number of packings)
	8 Net weight (kg) Gross weight (kg)

9 DECLARATION BY EXPORTER The undersigned declares that the information shown above is correct.

Place and date:... Signature:...

10 CERTIFICATION BY THE ISSUING BODY

It is hereby certified that the rice described above is one of the varieties of fragrant rice listed in Annex III of Commission Implementing Regulation (EU) No 2020/761 and that the information shown in this certificate is correct.

Place and date: Signature: Stamp:

11 FOR COMPETENT AUTHORITIES IN THE EUROPEAN UNION'

ANNEX II

Annexes I and II to Implementing Regulation (EU) 2020/1988 are amended as follows:

- (1) the tables referring to tariff quotas with order numbers 09.0144, 09.0145, and 09.0153 are deleted;
- (2) the table referring to tariff quota with order number 09.0141 is replaced by the following:

Order number	09.0141 - Husked rice 09.0165 - Paddy rice 09.0166 - Milled rice (medium-grained or long-grained) 09.0167 - Milled rice (round-grained) 09.0168 - Semi-milled rice (medium-grained or long-grained) 09.0169 - Semi-milled rice (round-grained)
Specific legal basis	Council Regulation (EC) No 1095/96 of 18 June 1996 on the implementation of the concessions set out in Schedule CXL drawn up in the wake of the conclusion of the GATT XXIV.6 negotiations
Product description and CN codes	Husked rice: 1006 20 Paddy rice: 1006 10 30 1006 10 50 1006 10 71 1006 10 79 Milled rice (medium-grained or long-grained): 1006 30 63 1006 30 65 1006 30 67 1006 30 94 1006 30 96 1006 30 98 Milled rice (round-grained): 1006 30 61 1006 30 92 Semi-milled rice (medium-grained or long-grained): 1006 30 23 1006 30 25 1006 30 27 1006 30 44 1006 30 46 1006 30 48 Semi-milled rice (round-grained): 1006 30 21 1006 30 42
TARIC codes	-

Origin	Bangladesh
Quantity	Equivalent to 4 000 000 kg of husked rice
Tariff quota period	1 January to 31 December
Tariff quota sub-periods	Not applicable
Proof of origin	Certificate of origin, in accordance with Article 13 of this Regulation
In-quota customs duty	For CN codes 1006 10 30, 1006 10 50, 1006 10 71 and 1006 10 79: the customs duties fixed in the Common Customs Tariff less 50 % and less a further EUR 4,34 For CN code 1006 20: the duty fixed in accordance with Article 183 of Regulation (EU) No 1308/2013 less 50 % and less a further EUR 4,34; For CN code 1006 30: the duty fixed in accordance with Article 183 of Regulation (EU) No 1308/2013 less EUR 16,78, less a further 50 % and less a further EUR 6,52.
Security to be lodged in accordance with Article 2 of Delegated Regulation (EU) 2020/1987	Not applicable
Specific conditions	In accordance with Article 13 of this Regulation'

(3) the table referring to tariff quotas with order numbers 09.0161 and 09.0162 is replaced by the following:

Order number	09.0161 - Bone-in 09.0162 - Boneless
Specific legal basis	Council Regulation (EC) No 1095/96 of 18 June 1996 on the implementation of the concessions set out in Schedule CXL drawn up in the wake of the conclusion of the GATT XXIV.6 negotiations Agreement in the form of an Exchange of Letters between the European Community and Australia pursuant to Article XXIV:6 and Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions in the schedules of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic in the course of their accession to the European Union ⁽¹⁾ , concluded by Council Decision 2006/106/EC ⁽²⁾ .
Product description and CN codes	Frozen beef intended for the manufacture of A- products: ex 0202 20 30 (see TARIC codes) ex 0202 30 10 (see TARIC codes) ex 0202 30 50 (see TARIC codes) ex 0202 30 90 (see TARIC codes) ex 0206 29 91 (see TARIC codes) "A-product" as defined in Article 18 of this Regulation

TARIC codes	0202 20 30 81 0202 20 30 82 0202 30 10 81 0202 30 10 82 0202 30 50 81 0202 30 50 82 0202 30 90 41 0202 30 90 42 0202 30 90 70 0206 29 91 33 0206 29 91 35 0206 29 91 51 0206 29 91 59
Origin	All third countries except the United Kingdom
Quantity	15 443 000 kg bone-in equivalent
Tariff quota period	1 July to 30 June
Tariff quota sub-periods	Not applicable
Proof of origin	Not applicable
In-quota customs duty	20 % ad valorem
Security to be lodged in accordance with Article 2 of Delegated Regulation (EU) 2020/1987	For CN code ex 0202 20 30: EUR 1 414 per 1 000 kg net weight For CN code ex 0202 30 10: EUR 2 211 per 1 000 kg net weight For CN code ex 0202 30 50: EUR 2 211 per 1 000 kg net weight For CN code ex 0202 30 90: EUR 3 041 per 1 000 kg net weight For CN code ex 0206 29 91: EUR 3 041 per 1 000 kg net weight
Specific conditions	In accordance with Articles 17 and 19 of this Regulation

(¹) OJ L 47, 17.2.2006, p. 54.

(²) Council Decision 2006/106/EC of 30 January 2006 on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and Australia pursuant to Article XXIV:6 and Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions in the schedules of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic in the course of their accession to the European Union (OJ L 47, 17.2.2006, p. 52).;

(4) the table referring to tariff quotas with order numbers 09.0163 and 09.0164 is replaced by the following:

Order number	09.0163 - Bone-in 09.0164 - Boneless
Specific legal basis	Council Regulation (EC) No 1095/96 of 18 June 1996 on the implementation of the concessions set out in Schedule CXL drawn up in the wake of the conclusion of the GATT XXIV.6 negotiations Agreement in the form of an Exchange of Letters between the European Community and Australia pursuant to Article XXIV:6 and Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions in the schedules of the Czech Republic, the Republic of Estonia, the

	Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic in the course of their accession to the European Union, concluded by Council Decision 2006/106/EC
Product description and CN codes	Frozen beef intended for the manufacture of B-products: ex 0202 20 30 (see TARIC codes) ex 0202 30 10 (see TARIC codes) ex 0202 30 50 (see TARIC codes) ex 0202 30 90 (see TARIC codes) ex 0206 29 91 (see TARIC codes) “B-product” as defined in Article 18 of this Regulation
TARIC codes	0202 20 30 83 0202 20 30 84 0202 30 10 83 0202 30 10 84 0202 30 50 83 0202 30 50 84 0202 30 90 43 0202 30 90 44 0202 30 90 75 0206 29 91 37 0206 29 91 38 0206 29 91 61 0206 29 91 69
Origin	All third countries, except the United Kingdom
Quantity	4 233 000 kg bone-in equivalent
Tariff quota period	1 July to 30 June
Tariff quota sub-periods	Not applicable
Proof of origin	Not applicable
In-quota customs duty	For CN code ex 0202 20 30: 20 % + EUR 994,5 per 1 000 kg net For CN code ex 0202 30 10: 20 % + EUR 1 554,3 per 1 000 kg net For CN code ex 0202 30 50: 20 % + EUR 1 554,3 per 1 000 kg net For CN code ex 0202 30 90: 20 % + EUR 2 138,4 per 1 000 kg net For CN code ex 0206 29 91: 20 % + EUR 2 138,4 per 1 000 kg net
Security to be lodged in accordance with Article 2 of Delegated Regulation (EU) 2020/1987	For CN code ex 0202 20 30: EUR 420 per 1 000 kg net weight For CN code ex 0202 30 10: EUR 657 per 1 000 kg net weight For CN code ex 0202 30 50: EUR 657 per 1 000 kg net weight For CN code ex 0202 30 90: EUR 903 per 1 000 kg net weight

	For CN code ex 0206 29 91: EUR 903 per 1 000 kg net weight
Specific conditions	In accordance with Articles 17 and 19 of this Regulation'

(5) the table referring to tariff quotas with order numbers 09.0159 and 09.0160 is replaced by the following:

Order number	09.0159 - Butter 09.0160 - Other
Specific legal basis	Council Regulation (EC) No 1095/96 of 18 June 1996 on the implementation of the concessions set out in Schedule CXL drawn up in the wake of the conclusion of the GATT XXIV.6 negotiations
Product description and CN codes	Butter and other fats and oils derived from milk: 0405 10 0405 90
TARIC codes	-
Origin	All third countries, except the United Kingdom
Quantity	11 360 000 kg in butter equivalent, divided as follows: 5 680 000 kg for each sub-period
Tariff quota period	1 July to 30 June
Tariff quota sub-periods	1 July to 31 December 1 January to 30 June
Proof of origin	Not applicable
In-quota customs duty	EUR 94,80 per 100 kg net weight
Security to be lodged in accordance with Article 2 of Delegated Regulation (EU) 2020/1987	Not applicable
Specific conditions	For CN code 0405 90: 1 kg product = 1,22 kg butter In accordance with Article 29 of this Regulation'

(6) in Annex II, the heading of Part B is replaced by the following:

B. Tariff quota under order numbers 09.0141, 09.0165, 09.0166, 09.0167, 09.0168 and 09.0169'.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/761**of 7 May 2021****amending Annexes I to IV to Implementing Regulation (EU) 2017/717 as regards the model forms of zootechnical certificates for breeding animals and their germinal products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation') ⁽¹⁾, and in particular Article 30(10) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2017/717 ⁽²⁾ lays down the model forms of zootechnical certificates for breeding animals and their germinal products. Those model forms of zootechnical certificates were drafted after consultation with the Member States and the relevant stakeholders.
- (2) Since the date of application of Implementing Regulation (EU) 2017/717, the Member States and stakeholders have notified the Commission of certain practical problems with the use of the model forms of zootechnical certificates, as regards the verification of the identity of breeding animals. Taking into account the experience gained since the date of application of that Implementing Regulation, the model forms of the zootechnical certificates should be amended to facilitate the verification of the identity of breeding animals. Details or the case number referring to the database where the details are available should be provided in a zootechnical certificate, in the box corresponding to results of the verification of the identity of breeding animals. Implementing Regulation (EU) 2017/717 should therefore be amended accordingly.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Zootechnics,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I to IV to Implementing Regulation (EU) 2017/717 are amended in accordance with the Annex to this Regulation.

Article 2

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

⁽¹⁾ OJ L 171, 29.6.2016, p. 66.

⁽²⁾ Commission Implementing Regulation (EU) 2017/717 of 10 April 2017 laying down rules for the application of Regulation (EU) 2016/1012 of the European Parliament and of the Council with regard to the model forms of zootechnical certificates for breeding animals and their germinal products (OJ L 109, 26.4.2017, p. 9).

It shall apply from 10 August 2021.

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

Done at Brussels, 7 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes I to IV to Implementing Regulation (EU) 2017/717 are amended as follows:

(1) Annex I is amended as follows:

- (a) in Section A, in the model form of Zootechnical certificate for trade in purebred breeding animals of the bovine, porcine, ovine and caprine species, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (b) in Section B, in the model form of Zootechnical certificate for trade in semen of purebred breeding animals, in footnote 9, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (c) in Section C, in the model form of Zootechnical certificate for trade in oocytes of purebred breeding animals, in footnote 9, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (d) in Section D, in the model form of Zootechnical certificate for trade in embryos of purebred breeding animals, in footnote 9, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’.

(2) Annex II is amended as follows:

- (a) in Section A, in the model form of Zootechnical certificate for trade in hybrid breeding pigs, in footnote 5, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (b) in Section B, in the model form of Zootechnical certificate for trade in semen of hybrid breeding pigs, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (c) in Section C, in the model form of Zootechnical certificate for trade in oocytes of hybrid breeding pigs, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (d) in Section D, in the model form of Zootechnical certificate for trade in embryos of hybrid breeding pigs, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’.

(3) Annex III is amended as follows:

- (a) in Section A, in the model form of Zootechnical certificate for entry into the Union of purebred breeding animals of the bovine, porcine, ovine, caprine and equine species, in footnote 5, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (b) in Section B, in the model form of Zootechnical certificate for entry into the Union of semen of purebred breeding animals, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (c) in Section C, in the model form of Zootechnical certificate for entry into the Union of oocytes of purebred breeding animals, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (d) in Section D, in the model form of Zootechnical certificate for entry into the Union of embryos of purebred breeding animals, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’.

(4) Annex IV is amended as follows:

- (a) in Section A, in the model form of Zootechnical certificate for entry into the Union of hybrid breeding pigs, in footnote 5, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (b) in Section B, in the model form of Zootechnical certificate for entry into the Union of semen of hybrid breeding pigs, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (c) in Section C, in the model form of Zootechnical certificate for entry into the Union of oocytes of hybrid breeding pigs, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’;

- (d) in Section D, in the model form of Zootechnical certificate for entry into the Union of embryos of hybrid breeding pigs Zootechnical certificate, in footnote 6, the following sentence is added:

‘Under “Result”, provide details or the case number referring to the database where the details are available.’.

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/762

of 6 May 2021

concerning the extension of the action taken by the Irish Department of Agriculture, Food and the Marine permitting the making available on the market and use of biocidal products containing propan-2-ol for use as human hygiene products in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2021) 3127)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular the third subparagraph of Article 55(1) thereof,

Whereas:

- (1) On 18 September 2020, the Irish Department of Agriculture, Food and the Marine ('the competent authority') adopted a decision in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit the making available on the market and use of biocidal products containing propan-2-ol for use as human hygiene products until 16 March 2021 ('the action'). The competent authority informed the Commission and the competent authorities of the other Member States about the action and the justification for it, in accordance with Article 55(1), second subparagraph, of that Regulation.
- (2) According to the information provided by the competent authority, the action was necessary in order to protect public health. The use of alcohol-based hand disinfectants has been recommended by the World Health Organization (WHO) as a preventative measure against the spread of COVID-19, as an alternative to washing hands with soap and water.
- (3) Propan-2-ol-based formulation recommended by WHO contains propan-2-ol as an active substance. Propan-2-ol is approved for use in biocidal products of product-type 1 (human hygiene) as defined in Annex V to Regulation (EU) No 528/2012.
- (4) Since the outbreak of the COVID-19 pandemic disinfection products have been in extremely high demand in Ireland, which led to unprecedented supply shortages of such products on the Irish market. COVID-19 represents a serious threat to public health in Ireland and having sufficient disinfection products is crucial for controlling its spread.
- (5) According to the conditions in the action, companies intending to make available on the market such products need to submit specific information on the products to the competent authority, which will decide whether to grant permission to make the products available on the market.
- (6) On 5 February 2021, the Commission received a reasoned request from the competent authority to be allowed to extend the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The request was made on the basis of concerns that public health might be endangered by COVID-19 beyond 16 March 2021 and taking into account that allowing additional disinfection products on the market is crucial in order to limit the danger posed by COVID-19.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

- (7) According to the competent authority, the demand for disinfection products for human hygiene remains extremely high due to the continued incidence of COVID-19 in Ireland.
- (8) The competent authority has encouraged all companies that made their products available on the market under the action to seek regular product authorisation as soon as possible, in order to minimise gaps in marketing of the products. Some companies applied for national authorisation of their products. However, a considerable amount of time is needed for the evaluation of the applications.
- (9) As COVID-19 continues to pose a danger to public health and such danger cannot be adequately contained in Ireland in the absence of additional disinfection products allowed on the market, it is appropriate to allow the competent authority to extend the action.
- (10) Considering that the action has lapsed since 17 March 2021, this Decision should have retroactive effect.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The Irish Department of Agriculture, Food and the Marine may extend the permit for the making available on the market and use of biocidal products containing propan-2-ol for use as human hygiene products until 18 September 2022.

Article 2

This Decision is addressed to the Irish Department of Agriculture, Food and the Marine.

It shall apply from 17 March 2021.

Done at Brussels, 6 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN