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⁽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.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/362

of 22 February 2021

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications ['Jabugo' (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 the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Spain's application for the approval of amendments to the specification for the designation of origin 'Jabugo', registered under Commission Regulation (EC) No 195/98 ⁽²⁾, as amended by Implementing Regulation (EU) 2017/385 ⁽³⁾.
- (2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ⁽⁴⁾ as required by Article 50(2)(a) of that Regulation.
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Jabugo' (PDO) are hereby approved.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Regulation (EC) No 195/98 of 26 January 1998 supplementing the Annex to Regulation (EC) No 2400/96 on the entry of certain names in the 'Register of protected designations of origin and protected geographical indications' provided for in Council Regulation (EEC) No 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (OJ L 20, 27.1.1998, p. 20).

⁽³⁾ Commission Implementing Regulation (EU) 2017/385 of 2 March 2017 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (Jamón de Huelva (PDO)) (OJ L 59, 7.3.2017, p. 33).

⁽⁴⁾ OJ C 352, 22.10.2020, p. 17.

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, 22 February 2021.

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

COMMISSION IMPLEMENTING REGULATION (EU) 2021/363**of 26 February 2021****concerning the authorisation of a preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159 as a feed additive for all animal species****(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 Article 9(2) 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159 as a feed additive for all animal species, to be classified in the additive category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 July 2020 ⁽²⁾ that, under the proposed conditions of use, the preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is not toxic by inhalation and the respiratory exposure is likely to be low but a risk of sensitisation via the respiratory route could not be excluded. The additive is non-irritant to skin and eyes and is not considered as a dermal sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the preparation concerned has the capability to degrade fumonisins in fermenting feed (with a fumonisin content within the limits operating in the Union) but only in silages, not in other fermenting feeds. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of fumonisin esterase produced by *Komagataella phaffii* DSM 32159 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised.
- (6) 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

The preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'substances for reduction of the contamination of feed by mycotoxins', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2020;18(7):6207

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, 26 February 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity/kg fresh material			
Category of technological additives. Functional group:substances for reduction of the contamination of feed by mycotoxins: fumonisins								
1m03i	Fumonisin esterase EC 3.1.1.87	Additive composition Preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159 containing a minimum of 3 000 U/g ⁽¹⁾ Characterisation of the active substance Preparation of fumonisin esterase produced by <i>Komagataella phaffii</i> DSM 32159. Analytical method ⁽²⁾ — For the determination of fumonisin esterase activity: High Performance Liquid Chromatography coupled with a tandem mass spectrometry. (HPLC-MS/MS) method based on the quantification of the tricarballic acid released from the action of the enzyme on fumonisin B1 at pH 8,0 and 30 °C.	All animal species	-	40	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. The use of the additive is only allowed in maize based silages. 3. Recommended maximum dose: 300 U/kg of fresh material. 4. The use of the additive is allowed in feeding-stuffs complying with European Union legislation on undesirable substances in animal feed ⁽³⁾ 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	21.3.2031

⁽¹⁾ 1 U is the enzymatic activity that releases 1 µmol tricarballic acid per minute from 100 µM fumonisin B1 in 20 mM Tris-Cl buffer pH 8,0 with 0,1 mg/ml bovine serum albumin at 30 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽³⁾ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

COMMISSION IMPLEMENTING REGULATION (EU) 2021/364**of 26 February 2021****approving active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product-type 1****(Text with EEA relevance)**

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 Article 9(1)(a) thereof,

Whereas:

- (1) On 31 July 2007, the competent authority of Slovakia ('the evaluating competent authority') received an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾, for the inclusion of the active substance active chlorine generated from sodium chloride by electrolysis in Annex I to that Directive for use in biocidal products of product-type 1, human hygiene, as defined in Annex V to that Directive, which corresponds to product-type 1 as defined in Annex V to Regulation (EU) No 528/2012.
- (2) On 19 November 2010, the evaluating competent authority submitted the assessment report together with its conclusions to the Commission in accordance with Article 11(2) of Directive 98/8/EC.
- (3) On 16 June 2020, the Biocidal Products Committee adopted the opinion of the European Chemicals Agency ⁽³⁾ ('the Agency'), having regard to the conclusions of the evaluating competent authority.
- (4) According to that opinion, biocidal products of product-type 1 using active chlorine generated from sodium chloride by electrolysis may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.
- (5) Taking into account the opinion of the Agency, it is appropriate to approve active chlorine generated from sodium chloride by electrolysis as an active substance for use in biocidal products of product-type 1 subject to compliance with certain specifications and conditions.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Active chlorine generated from sodium chloride by electrolysis is approved as an active substance for use in biocidal products of product-type 1 subject to the specifications and conditions set out in the Annex.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽³⁾ Biocidal Products Committee Opinion on the application for approval of the active substance active chlorine generated from sodium chloride by electrolysis, Product type:1, ECHA/BPC/250 adopted on 16 June 2020.

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, 26 February 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
Active chlorine generated from sodium chloride by electrolysis	IUPAC name: not applicable EC No: not applicable CAS No: not applicable Precursor: IUPAC Name: Sodium Chloride EC No 231-598-3 CAS No 7647-14-5	The specifications for active chlorine generated from sodium chloride by electrolysis in situ are dependent on the precursor sodium chloride which must comply with purity requirements of one of the following standards: NF Brand, EN 973 A, EN 973 B, EN 14805 Type 1, EN 14805 Type 2, EN 16370 Type 1, EN 16370 Type 2, EN 16401 Type 1, EN 16401 Type 2, CODEX STAN 150-1985 or European Pharmacopoeia 9.0.	1 July 2021	30 June 2031	1	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.

⁽¹⁾ The purity requirements for the precursor indicated in this column are those provided in the application for the approval of the active substance evaluated.

COMMISSION IMPLEMENTING REGULATION (EU) 2021/365**of 26 February 2021****approving active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-type 1****(Text with EEA relevance)**

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 Article 9(1)(a) thereof,

Whereas:

- (1) On 31 July 2007, the competent authority of Slovakia ('the evaluating competent authority') received an application, in accordance with Article 11(1) of Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾, for the inclusion of the active substance active chlorine released from hypochlorous acid in Annex I to that Directive for use in biocidal products of product-type 1, human hygiene, as defined in Annex V to that Directive, which corresponds to product-type 1 as defined in Annex V to Regulation (EU) No 528/2012.
- (2) On 19 November 2010, the evaluating competent authority submitted the assessment report together with its conclusions to the Commission in accordance with Article 11(2) of Directive 98/8/EC.
- (3) On 16 June 2020, the Biocidal Products Committee adopted the opinion of the European Chemicals Agency ⁽³⁾ ('the Agency'), having regard to the conclusions of the evaluating competent authority.
- (4) According to that opinion, biocidal products of product-type 1 using active chlorine released from hypochlorous acid may be expected to satisfy the requirements laid down in Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.
- (5) Taking into account the opinion of the Agency, it is appropriate to approve active chlorine released from hypochlorous acid as an active substance for use in biocidal products of product-type 1 subject to compliance with certain specifications and conditions.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Active chlorine released from hypochlorous acid is approved as an active substance for use in biocidal products of product-type 1 subject to the specifications and conditions set out in the Annex.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽³⁾ Biocidal Products Committee Opinion on the application for approval of the active substance active chlorine released from hypochlorous acid, Product type:1, ECHA/BPC/255 adopted on 16 June 2020.

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, 26 February 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
Active chlorine released from hypochlorous acid	IUPAC name: Hypochlorous acid EC No: 232-232-5 CAS No: 7790-92-3	Specification established for hypochlorous acid (as dry weight min. 90,87 % w/w) releasing active chlorine. Hypochlorous acid is the predominant species at pH 3,0 – 7,4.	1 July 2021	30 June 2031	1	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.

⁽¹⁾ The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

DECISIONS

COUNCIL DECISION (EU) 2021/366

of 22 February 2021

on the position to be adopted, on behalf of the European Union, in the Group of Experts on the European Agreement concerning the work of crews of vehicles engaged in international road transport (AETR) and in the Working Party on Road Transport of the United Nations Economic Commission for Europe

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The European Agreement concerning the work of crews of vehicles engaged in international road transport (AETR) ⁽¹⁾ entered into force on 5 January 1976. It was last amended on 20 September 2010.
- (2) Pursuant to Article 21 AETR, proposed amendments to the AETR may be submitted by any Contracting Party to the Secretary-General of the United Nations (UN). Before submission to the Secretary-General of the UN, the proposals are first discussed in the Working Party on Road Transport (SC.1) of the UN Economic Commission for Europe (UNECE).
- (3) A Group of Experts on the AETR has been established by UNECE in the framework of the AETR. That Group is a body empowered to develop and submit proposals to amend the AETR to the UNECE Working Party on Road Transport.
- (4) It is envisaged that the Group of Experts on the AETR, during its planned 25th session in February 2021, and the UNECE Working Party on Road Transport, during its planned 116th session in October 2021, will discuss amendments to the AETR relating to the adoption of the smart tachograph.
- (5) Article 22bis AETR provides that changes to Annex IB to Council Regulation (EEC) No 3821/85 ⁽²⁾ concerning the digital tachograph are automatically taken over by all Contracting Parties to the AETR without any formal consultation or vote. The lack of participation of the Contracting Parties to the AETR in the process of development and adoption of technical specifications on the digital tachograph has been a cause of discontent among some of those Contracting Parties. The Commission acknowledges in its communication of 19 July 2011 entitled 'Digital Tachograph: Roadmap for future activities' that this mechanism jeopardises the correct and harmonised implementation of the digital tachograph by non-Union Contracting Parties.
- (6) It is in the interest of the Union that the decision-making process envisaged in the AETR as regards control devices, including digital tachographs, be modified, that the procedure set out in Article 22(1), (2) and (3) AETR become applicable to the inclusion of the technical specifications of the smart tachograph in the AETR, and that Article 22bis AETR remain in force for possible future amendments to the requirements for the previous versions of the tachograph.

⁽¹⁾ OJ L 95, 8.4.1978, p. 1.

⁽²⁾ Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport (OJ L 370, 31.12.1985, p. 8).

- (7) Pursuant to Article 10 AETR, a tachograph whose construction, installation, use and testing are carried out in accordance with Regulation (EEC) No 3821/85 is considered to comply with the requirements of the AETR. Article 10 AETR should be amended in order to include a reference to the technical specifications of the smart tachograph, which should be considered to comply with the requirements of the AETR as from the date of entry into force of Appendix 1C to the Annex to the AETR.
- (8) Article 13 AETR, which concerns transitional provisions, should be amended to set out the precise date for the implementation by the Contracting Parties of the provisions on smart tachographs.
- (9) Article 14 AETR does not allow for the accession of bodies other than States members of UNECE and States admitted to UNECE in a consultative capacity.
- (10) There are several arguments in favour of allowing the Union to accede to the AETR. Firstly, the Union has exclusive competence in the area of the work of crews of vehicles engaged in international road transport, as confirmed by the Court of Justice of the European Union in Case 22/70 ⁽³⁾. Secondly, the Union's accession to the AETR would guarantee the effective representation of the Union's interests within the AETR. Finally, the specificities of the AETR and of the proposed decision-making process make it appropriate for the Union to be a Contracting Party. In order to allow for the accession of the Union to the AETR, Article 14 AETR should be amended in order to provide for the accession of regional integration organisations to the AETR.
- (11) The technical specifications of the smart tachograph to be included in the AETR as Appendix 1C to the Annex thereto should be developed on the basis of the specifications submitted to the Group of Experts on the AETR on behalf of the Union on 8 April 2020 and on the basis of the specifications to be adopted by the Commission in 2021 under Regulation (EU) No 165/2014 of the European Parliament and of the Council ⁽⁴⁾.
- (12) The model for the approval certificate in Chapter III of Appendix 2 to the Annex to the AETR should be amended so that it can also be used for the approval of smart tachographs and its components.
- (13) It is appropriate to establish the position to be taken on the Union's behalf in the Group of Experts on the AETR and in the UNECE Working Party on Road Transport, as the AETR should be amended in order to achieve pan-European harmonisation in the field of recording equipment in road transport (tachographs), and such amendments will produce legal effects as referred to in Article 218(9) TFEU.
- (14) As the Union is not a Contracting Party to the AETR and its status does not allow it to communicate the proposed amendments, Member States, acting in the interest of the Union, should communicate the proposed amendments to the Group of Experts on the AETR in the spirit of loyal cooperation in order to promote the achievement of the Union's objectives.
- (15) The Union's position is to be expressed by the Member States of the Union that are members of the Group of Experts on the AETR and of the UNECE Working Party on Road Transport, acting jointly,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf in the 25th session of the Group of Experts on the European Agreement concerning the work of crews of vehicles engaged in international road transport (AETR) and in the 116th session of the UNECE Working Party on Road Transport shall be in accordance with the proposed amendments to the AETR ⁽⁵⁾.

⁽³⁾ ECLI:EU:C:1971:32.

⁽⁴⁾ Regulation (EU) No 165/2014 of the European Parliament and of the Council of 4 February 2014 on tachographs in road transport, repealing Council Regulation (EEC) No 3821/85 on recording equipment in road transport and amending Regulation (EC) No 561/2006 of the European Parliament and of the Council on the harmonisation of certain social legislation relating to road transport (OJ L 60, 28.2.2014, p. 1).

⁽⁵⁾ See document ST 5700/21 at <http://register.consilium.europa.eu>

Formal and minor changes to the position referred to in the first paragraph may be agreed without a further decision of the Council.

Article 2

1. The position referred to in Article 1 shall be expressed by the Member States of the Union that are members of the Group of Experts on the AETR and of the UNECE Working Party on Road Transport, acting jointly.
2. The Member States shall communicate the proposed amendments to the Group of Experts on the AETR.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 22 February 2021.

For the Council
The President
J. BORRELL FONTELLES

CORRIGENDA**Corrigendum to Council Decision (EU) 2021/357 of 25 February 2021 amending Decision 98/683/EC concerning exchange rate matters relating to the CFA franc and the Comorian franc**

(Official Journal of the European Union L 69 of 26 February 2021)

On the cover, in the table of contents, and on page 1, in the title:

for: 'Council Decision (EU) 2021/357 of 25 February 2021 amending Decision 98/683/EC concerning exchange rate matters relating to the CFA franc and the Comorian franc',

read: 'Council Decision (EU) 2021/357 of 25 January 2021 amending Decision 98/683/EC concerning exchange rate matters relating to the CFA franc and the Comorian franc'.

On page 3:

for: 'Done at Brussels, 25 February 2021.',

read: 'Done at Brussels, 25 January 2021.'.

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