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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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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information concerning the date of entry into force of the Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, to take account of the accession of the Republic of Croatia to the European Union

The abovementioned Protocol between the European Union and the State of Israel, signed in Brussels on 20 December 2018, entered into force on 1 October 2020.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1369

of 29 September 2020

amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽¹⁾, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) Regulation (EEC) No 2658/87 establishes a goods nomenclature (hereinafter referred to as the 'Combined Nomenclature' or 'CN') to meet, at one and the same time, the requirements of the Common Customs Tariff, the external trade statistics of the Union, and other Union policies concerning the importation or exportation of goods.
- (2) That Regulation also establishes an Integrated Tariff of the European Union (hereinafter referred to as the 'TARIC'), which meets the requirements of the Common Customs Tariff, external trade statistics, the commercial, agricultural and other Union policies concerning the importation or exportation of goods.
- (3) In order for the Union to monitor statistics related solely to the importation of specific goods, the creation of statistical subheadings in TARIC is the most appropriate tool; such TARIC statistical codes are laid down in Annex 10 'Statistical TARIC codes' of Part Three (Tariff Annexes) of Annex I to Regulation (EEC) No 2658/87.
- (4) The COVID-19 pandemic situation is ongoing in the Union and, therefore, the demand for certain medical goods in the Member States, in particular protective face masks, is high and imports of such goods brings additional challenges to the customs authorities.
- (5) The increasing use of and demand for protective face masks in the Union is significant in the current situation as Member States are fighting against the spread of COVID-19 and its importance will likely remain high into the future.
- (6) In order to facilitate and harmonise the customs controls in the Member States at Union level, it is appropriate to create additional TARIC subheadings corresponding to a higher level of detail for different protective face masks, in accordance with their filtering capacities. These additional subheadings would allow to faster distinguish the products concerned from others under the same subheading, thus mitigating the impact of possible delays in the supply chain during the pandemic.
- (7) In addition, such additional TARIC subheadings should be created in order to ensure better monitoring of the trade flows of these protective face masks.

⁽¹⁾ OJ L 256, 7.9.1987, p. 1.

- (8) Such additional TARIC subheadings would also facilitate the implementation by Member States of Commission Decision (EU) 2020/491 ⁽²⁾. As protective face masks are amongst the most imported products, their specific identification in the TARIC would allow for a quicker declaration process by distinguishing such products from other products currently classified under the same subheading.
- (9) Annex 10 in Part Three of Annex I to Regulation (EEC) No 2658/87 should therefore be amended accordingly.
- (10) In order for the customs authorities, which are implementing Commission Decision (EU) 2020/491, to benefit from this measure as soon as possible and to facilitate the fast supply chain of such products, this Regulation should therefore enter into force as a matter of urgency.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EEC) No 2658/87 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 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, 29 September 2020.

*For the Commission,
On behalf of the President,
Gerassimos THOMAS
Director-General
Directorate-General for Taxation and Customs Union*

⁽²⁾ Commission Decision (EU) 2020/491 of 3 April 2020 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020 (OJ L 103I, 3.4.2020, p. 1).

ANNEX

Annex I to Regulation (EEC) No 2658/87 is amended as follows:

(1) in Part Two, Section XI, Chapter 63, the row for CN code 6307 90 98 is replaced by the following:

6307 90 98	---- Other (*)	6,3	-
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(*) Statistical TARIC codes: See Annex 10.;

(2) in Part Three, in Annex 10, the following rows are inserted:

6307 90 98	---- Other:	
	----- Nonwovens:	
	----- Protective face masks:	
6307 90 98 11	----- Filtering facepieces FFP2 and FFP3 according to EN149, and other masks filtering at least 94 % of 0,3 micron particles	p/st
	----- Other:	
6307 90 98 13	----- Filtering facepieces FFP1 according to EN149, and other masks filtering at least 80 % of 0,3 micron particles	p/st
	----- Other:	
6307 90 98 15	----- Medical face masks according to EN14683, and other masks filtering at least 95 % of 3,0 micron particles	p/st
6307 90 98 17	----- Other	p/st
6307 90 98 19	----- Other	-
	----- Other:	
6307 90 98 91	----- Hand-made	-
6307 90 98 99	----- Other	-'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1370**of 1 October 2020****concerning the authorisation of a preparation of lanthanide citrate as a feed additive for weaned piglets (holder of authorisation Treibacher Industrie AG)****(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 lanthanide citrate. 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 the preparation of lanthanide citrate as a feed additive for weaned piglets to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 16 April 2013 ⁽²⁾, 20 April 2016 ⁽³⁾ and 12 November 2019 ⁽⁴⁾ that, under the proposed conditions of use, the preparation of lanthanide citrate does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that although the acute respiratory toxicity data indicate that the dust is of low toxicity, prolonged or repeated exposure to the additive should be avoided. 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 additive has the potential to be efficacious in improving the growth of weaned piglets. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method 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 lanthanide citrate 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 as specified in the Annex to this Regulation.
- (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 'zootechnical additives' and to the functional group 'other zootechnical additives', 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 2013; 11(5):3206.

⁽³⁾ EFSA Journal 2016; 14(5):4477.

⁽⁴⁾ EFSA Journal 2019; 17(12):5912.

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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	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
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters).									
4d21	Treibacher Industrie AG	Lanthanide citrate	Additive composition Preparation of lanthanide citrate containing: Lanthanide citrate ≥ 65 % Sodium 8-12 % Chloride 8-12 % Water < 10 % Solid form Characterisation of active substance Lanthanide citrate Lanthanum 8,5 ± 0,9 % Chemical formula C ₆ H ₅ LaO ₇ CAS-Number: 3002-52-6 Cerium 16,3 ± 1,6 %, Chemical formula: C ₆ H ₅ CeO ₇ CAS-Number: 512-24-3 Citrate 40 ± 5 %. Chemical formula: C ₆ H ₅ O ₇ CAS number: 126-44-3 Analytical method ⁽¹⁾ For the quantification of citrate salts: Titration – European Pharmacopeia Monographs 0400 and 0412 For the quantification of total lanthanum and total cerium: Inductively Coupled Plasma-Mass Spectrometry (ICP-MS)	Weaned piglets	- <				

⁽¹⁾ 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1371**of 1 October 2020****concerning the authorisation of a preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase as a feed additive for lactating sows (holder of the authorisation BASF SE)****(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 endo-1,4-beta-xylanase and endo-1,4-beta-glucanase. 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 endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* DSM 18 404 as a feed additive for lactating sows to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 January 2020 ⁽²⁾ that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* DSM 18 404 does not have an adverse effect on animal health, consumer safety or the environment. It was also concluded that the additive should be considered as a potential skin and respiratory 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 concluded that the additive is efficacious as a zootechnical additive in improving the digestibility of the diets in lactating sows. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method 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 endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Aspergillus niger* CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Aspergillus niger* DSM 18 404 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 as specified in the Annex to this Regulation.
- (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 'zootechnical additives' and to the functional group 'digestibility enhancers', 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(2):6025.

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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	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 of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers.

4a7	BASF SE	Endo-1,4-beta-xylanase (EC 3.2.1.8) and endo-1,4-beta-glucanase (EC 3.2.1.4)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Aspergillus niger</i> CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by <i>Aspergillus niger</i> DSM 18 404 having a minimum activity of 5 600 TXU ⁽¹⁾ and 2 500 TGU ⁽²⁾ /g in solid or liquid form	Lactating sows	-	560 TXU 250 TGU	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their 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 skin, eyes and breathing protection.	22 October 2030
			<i>Characterisation of active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Aspergillus niger</i> CBS 109.713 and endo-1,4-beta-glucanase (EC 3.2.1.4) produced by <i>Aspergillus niger</i> DSM 18 404						
			<i>Analytical method</i> ⁽³⁾ For quantification of endo-1,4-beta-xylanase in the feed additive, premixtures and feed materials and compound feed: Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta-xylanase on the xylan containing substrate (wheat arabinoxylan) at pH = 3,5 and 55 °C. For quantification of endo-1,4-beta-glucanase in the feed additive, premixtures, feed materials and compound feed: Viscosimetric method based on decrease of viscosity produced by action of endo-1,4-beta-glucanase on the glucan containing substrate (barley betaglucan) at pH = 3,5 and 40 °C.						

⁽¹⁾ One TXU is defined as the amount of enzyme that liberates 5 µmol of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH = 3,5 and 55 °C.

⁽²⁾ One TGU is defined as the amount of enzyme that liberates 1 µmol of reducing sugars (glucose equivalents) from barley betaglucan per minute at pH = 3,5 and 40 °C.

⁽³⁾ 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1372

of 1 October 2020

concerning the authorisation of L-tryptophan produced by *Escherichia coli* CGMCC 7.267, CGMCC 11 674 or KCCM 10 534 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 applications were submitted for the authorisation of L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534. These applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The applications concern the authorisation of L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 26 February 2019 ⁽²⁾, 28 January 2020 ⁽³⁾, 18 March 2020 ⁽⁴⁾ and 25 May 2020 ⁽⁵⁾ that, under the proposed conditions of use, L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 does not have an adverse effect on the health of non-ruminant animals, consumer safety or the environment. To be safe for ruminants, the L-tryptophan should be protected against degradation in the rumen. The Authority stated a risk for the users of the additive upon inhalation due to the endotoxin levels of the L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 and could not exclude a potential of L-tryptophan produced by *Escherichia coli* CGMCC 11 674 or *Escherichia coli* CGMCC 7.267 to be an irritant to skin and eyes or to be a skin 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.
- (5) The Authority considered L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 an efficacious source of the essential amino acid tryptophan for non-ruminant animals; for the supplemental L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 to be fully efficacious in ruminants, it should be protected against degradation in the rumen. In its opinions, the Authority raised concerns about potential nutritional imbalances for amino acids, when they are administered via water for drinking. However, the Authority did not propose a maximum content for the supplementation with L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534. Thus, it is appropriate to indicate on the label of the additive, and premixtures containing it, an alert to take into account the dietary supply with all the essential and conditionally essential amino acids, particularly in the case of supplementation with L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 as amino acid via water for drinking. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2019; 17(3):5642.⁽³⁾ EFSA Journal 2020;18(2):6013.⁽⁴⁾ EFSA Journal 2020;18(4):6071.⁽⁵⁾ EFSA Journal 2020;18(6):6168.

- (6) The assessment of L-tryptophan produced by *Escherichia coli* CGMCC 7.267, *Escherichia coli* CGMCC 11 674 or *Escherichia coli* KCCM 10 534 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 substance should be authorised as specified in the Annex to this Regulation.
- (7) 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 substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	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
						mg/kg of complete feed with a moisture content of 12 %			

Category of nutritional additives. Functional group: amino acids, their salts and analogues.

3c441	-	L-tryptophan	Additive composition: Powder with a minimum of 98 % L-tryptophan (on a dry matter basis) Maximum content of 10 mg/kg 1,1'-ethylidene-bis-L-tryptophan (EBT) Characterisation of the active substance: L-tryptophan produced by fermentation with <i>Escherichia coli</i> CGMCC 7.267 or <i>Escherichia coli</i> KCCM 10 534 or <i>Escherichia coli</i> CGMCC 11674 Chemical formula: C₁₁H₁₂N₂O₂ CAS No: 73-22-3 Analytical methods ⁽¹⁾: For the identification of L-tryptophan in the feed additive: — Food Chemical Codex 'L-tryptophan monograph'. For the determination of tryptophan in the feed additive and premixtures: — High performance liquid chromatography with fluorescence detection (HPLC-FLD) – EN ISO 13 904 For the determination of tryptophan in compound feed and feed materials: — High Performance Liquid Chromatography with fluorescence detection (HPLC-FLD) – Commission Regulation (EC) No 152/2009 (Annex III, G)	All species	-	-	-	1. L-tryptophan may be placed on the market and used as an additive consisting of a preparation. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. 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, safety glasses and gloves. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1600 IU endotoxins/m³ air ⁽²⁾. 4. L-tryptophan may be used via water for drinking. 5. For ruminants, L-tryptophan shall be rumen protected.	22.10.2030
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			For the determination of tryptophan in water: — High performance liquid chromatography with fluorescence detection (HPLC-FLD)					6. The labelling of the additive and premixtures shall indicate the following: ‘The supplementation with L-tryptophan, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in order to avoid imbalances.’ 7. Declarations to be made on the label of the additive: Moisture content.	
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⁽¹⁾ 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>

⁽²⁾ Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6013 and EFSA Journal 2020;18(4):6071); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1373**of 1 October 2020****concerning the authorisation of zinc chelate of lysine and glutamic acid 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 zinc chelate of lysine and glutamic acid. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of zinc chelate of lysine and glutamic acid as a feed additive for all animal species to be classified in the additive category 'nutritional additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 July 2019 ⁽²⁾ that, under the proposed conditions of use, zinc chelate of lysine and glutamic acid does not have an adverse effect on animal health and consumer health. It also concluded that the additive is considered as a potential skin and respiratory sensitizer and stated a risk for the users of the additive upon inhalation. Therefore, 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 that additive does not pose an additional risk for the environment compared to other compounds of zinc and that it is an efficacious source of zinc for all animal species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method 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 that additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are, subject to the relevant protective measures for the users of the additive, satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.
- (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 substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', 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 2019;17(7):5782.

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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	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
						Content of element (Zn) in mg/kg of complete feed with a moisture content of 12 %			

Category of nutritional additives. Functional group: compounds of trace elements

3b615	-	Zinc chelate of lysine and glutamic acid	Additive composition: Mixture of chelates of zinc with lysine and chelates of zinc with glutamic acid in a ratio of 1:1 as a powder with a zinc content between 17 and 19 %, a lysine content between 19 and 21 %, a glutamic acid content between 21 and 23 % and a maximum of 3 % moisture	All animal species	-	-	Dogs and cats: 200 (total) Salmonids and milk replacers for calves: 180 (total) Piglets, sows, rabbits and all fish other than salmonids: 150 (total) Other species and categories: 120 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Zinc chelate of lysine and glutamic acid may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing protection.	22.10.2030.
			Characterisation of the active substances: Chemical formulas: Zinc-2,6-diaminohexanoic acid, chloride and hydrogen sulfate salt: $C_6H_{19}ClN_2O_8SZn$ Zinc-2-aminopentanedioic acid, sodium and hydrogen sulfate salt: $C_5H_8NNaO_8SZn$						
			Analytical methods *: For the quantification of the lysine and glutamic acid content in the feed additive: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) For the quantification of total zinc in the feed additive: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15 621) or — atomic absorption spectrometry, AAS (ISO 6869)						

Identification number of the additive	Name of the holder of authorisation	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
						Content of element (Zn) in mg/kg of complete feed with a moisture content of 12 %			
			For proving the chelated structure of the feed additive: — mid-infrared (IR) spectrometry together with the determination of the content of the trace element and lysine and glutamic acid in the feed additive For the quantification of total zinc in premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15 510 or EN 15 621) or — atomic absorption spectrometry, AAS (ISO 6869) or — inductively coupled plasma mass spectrometry, ICP-MS (EN 17 053) For the quantification of total zinc in feed materials and compound feed: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15 510 or EN 15 621) or — atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or — inductively coupled plasma mass spectrometry, ICP-MS (EN 17 053)						

* 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1374**of 1 October 2020****concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for calves, all minor ruminant species (for rearing) other than lambs and camelids (for rearing) (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)****(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 the preparation of *Saccharomyces cerevisiae* CNCM I-1077. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for calves, all minor ruminant species (for rearing) other than lambs and camelids (for rearing), to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 May 2019 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1077 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that this preparation is considered an eye irritant. 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 has the potential to be efficacious in improving weight gain and feed to gain ratio. The conclusion on efficacy for calves can be extrapolated to minor ruminant species and camelids at the same developmental stage. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method 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 *Saccharomyces cerevisiae* CNCM I-1077 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 as specified in the Annex to this Regulation.
- (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***Authorisation**

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', 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 2019;17(6):5723.

*Article 2***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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers.									
4b1711	Danstar Ferment AG represented in the Union by Lallemand SAS	Saccharomyces cerevisiae CNCM I-1077	Additive composition Preparation of <i>Saccharomyces cerevisiae</i> CNCM I-1077 containing a minimum of: — 1 × 10 ¹⁰ CFU/g additive (coated form) — 2 × 10 ¹⁰ CFU/g additive (not-coated form)	Calves All minor ruminant species (for rearing) other than lambs Camelids (for rearing)	-	1 × 10 ⁹	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their 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 skin, eyes and breathing protection.	22.10.2030
			Characterisation of active substance Viable cells of <i>Saccharomyces cerevisiae</i> CNCM I-1077						
			Analytical method ⁽¹⁾ Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15 789:2009). Identification: polymerase chain reaction (PCR) method (CEN/TS 15 790:2008)						

⁽¹⁾ 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1375**of 1 October 2020****concerning the authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for suckling piglets, turkeys for fattening and turkeys reared for breeding (holder of authorisation Vetagro SpA)****(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, applications were submitted for the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin. Those applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) Those applications concern the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for suckling piglets, turkeys for fattening and turkeys reared for breeding, to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 July 2019 ⁽²⁾ that, under the proposed conditions of use, the preparation of citric acid, sorbic acid, thymol and vanillin does not have an adverse effect on animal health, consumer safety or the environment. The Authority also concluded that the additive is considered a potential skin/eyes irritant and a skin 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 concluded that the additive has the potential to be efficacious in improving zootechnical performance in chickens for fattening and this conclusion can be extended to chickens reared for laying and to minor poultry species reared for laying ⁽³⁾. Based on this, in its opinion of 2019 the Authority has extrapolated the conclusions reached in chickens for fattening to turkeys for fattening and turkeys reared for breeding. It was also concluded that the additive has the potential to be efficacious in improving zootechnical performance in suckling piglets, at a recommended dose, by extending the conclusion reached in weaned piglets ⁽⁴⁾. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method 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 citric acid, sorbic acid, thymol and vanillin 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 as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2019;17(7):5795.

⁽³⁾ EFSA Journal 2012;10(5):2670.

⁽⁴⁾ EFSA Journal 2012;10(5):2670.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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, 1 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	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
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)

4d3	Vetagro SpA	Preparation of protected citric acid, sorbic acid, thymol and vanillin	<i>Additive composition:</i> Preparation of protected microbeads containing citric acid, sorbic acid, thymol and vanillin with a minimum of: Citric acid: 25 g/100 g Thymol: 1,7 g/100 g Sorbic acid: 16,7 g/100 g Vanillin: 1 g/100 g	Suckling piglets	-	1 000	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Indicate in the instruction of use: 'The total maximum content by the different sources of citric acid and sorbic acid in complete feed shall not be exceeded' 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their 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 skin, eyes and breathing protection.	22.10.2030
			<i>Characterisation of active substance:</i> Citric acid C₆H₈O₇ (purity ≥ 99,5 %) 2-hydroxy-1,2,3-propanetricarboxylic acid, CAS number 77-92-9 anhydrous Sorbic acid C₆H₈O₂ (purity ≥ 99, 5 %) 2,4-hexadienoic acid, CAS number 110-44-1 Thymol (purity ≥ 98 %) 5-methyl-2-(1-methylethyl)phenol, CAS number 89-83-8) Vanillin (purity ≥ 99, 5 %) 4-hydroxy-3-methoxybenzaldehyde, CAS number 121-33-5) <i>Analytical method ⁽¹⁾:</i> Determination of sorbic acid and thymol in feed additive, premixtures and feedingstuffs: — Reversed phase high performance liquid chromatography equipped with ultraviolet/diode array detection (RP-HPLC-UV/DAD)		-	200	-		

			Determination of citric acid in the additive and premixtures: — Reversed phase high performance liquid chromatography equipped with ultraviolet/diode array detection (RP-HPLC-UV/DAD) Determination of citric acid in feedingstuffs: — enzymatic determination of citric acid content – NADH (reduced form of nicotinamide adenine dinucleotide) spectrometric method							
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⁽¹⁾ 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1376**of 1 October 2020****concerning the authorisation of a preparation of 6-phytase, produced by *Komagataella phaffii* (CGMCC 12056) as feed additive for turkeys for fattening, turkeys reared for breeding, piglets (suckling and weaned) and minor porcine species (holder of the authorisation Andrés Pinaluba S.A)****(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, two applications were submitted for the authorisation of a preparation of 6-phytase, produced by *Komagataella phaffii* (CGMCC 12056). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) Those applications concern the authorisation of the preparation of 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) as a feed additive for turkeys for fattening, turkeys reared for breeding, piglets (suckling and weaned) and minor porcine species to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 7 October 2019 ⁽²⁾ that, under the proposed conditions of use, the preparation of 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive should be regarded as a respiratory 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 concluded that the additive showed improvements on the phosphorus utilisation and content. This conclusion can be extended to turkeys reared for breeding. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method 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 6-phytase produced by *Komagataella phaffii* (CGMCC 12056) 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 as specified in the Annex to this Regulation.
- (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 'zootechnical additives' and to the functional group 'digestibility enhancers', 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 2019;17(11):5893 and EFSA Journal 2019;17(11):5894.

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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	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
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers

4a31	Andrés Pintaluba S.A.	6-phytase EC 3.1.3.26	<i>Additive composition</i> Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Komagataella phaffii</i> (CGMCC 12056) having a minimum activity of: Solid form: 20 000 U ⁽¹⁾ /g Liquid form: 20 000 U/ml	Turkeys for fattening Turkeys reared for breeding Piglets (suckling and weaned) Minor porcine species (suckling and weaned)	-	250 U	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. 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.	22 October 2030
			<i>Characterisation of the active substance:</i> 6-phytase (EC 3.1.3.26) produced by <i>Komagataella phaffii</i> (CGMCC 12056)						
			<i>Analytical method ⁽²⁾</i> For the quantification of phytase activity in the feed additive: — colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.4 For the quantification of phytase activity in premixtures: — colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.3 For the quantification of phytase activity in feedingstuffs: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024						

⁽¹⁾ One unit is the amount of enzyme which releases one micromole of inorganic phosphate from phytate per minute at pH 5,5 and 37 °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>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1377

of 1 October 2020

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) as a feed additive for suckling piglets, all minor porcine species other than reproductive animals (holder of authorisation Beldem, a division of Puratos NV)

(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 endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136). This application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) as a feed additive for all porcine species, to be classified in the additive category 'zootechnical additives'.
- (4) The additive was authorised for 10 years by Commission Implementing Regulation (EU) 2017/211 ⁽²⁾ for poultry, weaned piglets and pigs for fattening.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 October 2019 ⁽³⁾ that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is considered as a potential respiratory sensitiser and that no conclusion could be drawn on dermal sensitisation potential by the additive. 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, in its previous opinion ⁽⁴⁾, concluded that the additive showed improvements of zootechnical performance in weaned piglets and pig for fattening and this conclusion can be extrapolated to all porcine species from suckling to slaughter, but efficacy has not been demonstrated for sows or other porcine species for reproduction. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) 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 as specified in the Annex to this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Implementing Regulation (EU) 2017/211 of 7 February 2017 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) as a feed additive for poultry, weaned piglets and pigs for fattening, and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005, and (EC) No 322/2009 and repealing Regulation (EC) No 516/2007 (holder of authorisation Beldem, a division of Puratos NV). OJ L 33, 8.2.2017, p. 23.⁽³⁾ EFSA Journal 2019;17(11):5892.⁽⁴⁾ EFSA Journal 2016;14(9):4562.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	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
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers

4a1606i	Beldem a division of Puratos NV	Endo-1,4-beta-xylanase EC 3.2.1.8	Additive composition: Preparation of endo-1,4-beta-xylanase produced by <i>Bacillus subtilis</i> LMG S-15136 having a minimum activity of: 400 IU ⁽¹⁾ /g Solid form and liquid form	Suckling piglets Minor porcine species other than reproductive animals	-	10 IU	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. 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 and skin protection.	22.10.2030
			Characterisation of the active substance: Endo-1,4-beta-xylanase produced by <i>Bacillus subtilis</i> LMG S-15136						
			Analytical method ⁽²⁾ For the quantification of endo-1,4-beta-xylanase activity in the feed additive: — colorimetric method measuring reducing sugars released by action of endo-1,4-beta-xylanase on birchwood xylan substrate in the presence of 3,5-dinitrosalicylic acid (DNS). For the quantification of endo-1,4-beta-xylanase activity in premixtures and feedingstuffs: — colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked arabinoxylan substrates.						

⁽¹⁾ One IU is the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalent) per minute from birchwood xylan at pH 4,5 and 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1378**of 1 October 2020****concerning the authorisation of copper chelate of lysine and glutamic acid 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 copper chelate of lysine and glutamic acid. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of copper chelate of lysine and glutamic acid as a feed additive for all animal species to be classified in the additive category 'nutritional additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 May 2019 ⁽²⁾ that, under the proposed conditions of use, copper chelate of lysine and glutamic acid does not have an adverse effect on animal health and consumer safety. It also concluded that the additive is an eye irritant, skin and respiratory sensitizer, and stated a risk for the users of the additive upon inhalation. 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 that additive does not pose an additional risk for the environment compared to other compounds of copper and that it is an efficacious source of copper for all animal species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method 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 that additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are, subject to the relevant protective measures for the users of the additive, satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.
- (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 substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', 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 2019;17(6):5728.

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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b415	—	Copper chelate of lysine and glutamic acid	<i>Additive composition</i> Mixture of chelate of copper with lysine and chelate of copper with glutamic acid in a ratio of 1:1 as a powder with a copper content between 17 and 19 %, a lysine content between 19 and 21 %, a glutamic acid content between 19 and 21 % and a maximum of 3 % moisture	All animal species	—	—	Bovines: — Bovines before the start of rumination: 15 (total); — Other bovines: 30 (total). — Ovines: 15 (total). Caprines: 35 (total) Piglets: — suckling and weaned up to 4 weeks after weaning: 150 (total). — from 5-th week after weaning up to 8 weeks after weaning: 100 (total). Crustaceans: 50 (total). Other animals: 25 (total).	1. The additive shall be incorporated into feed in the form of a premixture. 2. Copper chelate of lysine and glutamic acid may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 4. The following words shall be included in the labelling: — For feed for ovines if the level of copper in the feed exceeds 10 mg/kg:	22 October 2030

Identification number of the additive	Name of the holder of authorisation	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
						Content of element (Cu) in mg/kg of complete feed with a moisture content of 12 %			
			— atomic absorption spectrometry, AAS (ISO 6869) For proving the chelated structure of the feed additive: — mid-infrared (IR) spectrometry together with the determination of the content of the trace element and lysine and glutamic acid in the feed additive For the quantification of total Cu in premixtures: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869) or — inductively coupled plasma mass spectrometry, ICP-MS (EN 17053) For the quantification of total Cu in feed materials and compound feed: — inductively coupled plasma atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C or ISO 6869) or — inductively coupled plasma mass spectrometry, ICP-MS (EN 17053)					‘The level of copper in this feed may cause poisoning in certain breeds of sheep.’ — For feed for bovines after the start of rumination if the level of copper in the feed is less than 20 mg/kg: ‘The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur.’	

(¹) 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>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1379

of 1 October 2020

concerning the authorisation of L-cystine produced by *Pantoea ananatis* NITE BP-02525 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 L-cystine produced by *Pantoea ananatis* NITE BP-02525 as a feed additive in feed and water for drinking for all animal species. 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 L-cystine produced by *Pantoea ananatis* NITE BP-02525 as a feed additive for all animal species to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues', and in the additive category 'sensory additives', functional group 'flavouring compounds'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 January 2020 ⁽²⁾ that, under the proposed conditions of use, L-cystine produced by *Pantoea ananatis* NITE BP-02525 does not have an adverse effect on animal health, consumers health or the environment, and that it is slightly irritating by inhalation. 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. Moreover, the Authority stated that the supplementation with L-cystine produced by fermentation with *Pantoea ananatis* NITE BP-02525 should respect the requirements for sulphur-containing amino acids. Therefore, a respective labelling provision should be established. The Authority also concluded that the additive may be considered efficacious to contribute to the requirements for sulphur-containing amino acids in all animal species and that for the supplemental L-cystine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority expressed in its opinion a concern over potential nutritional imbalances of when L-cystine is administered as amino acid via water for drinking. However, no maximum content for L-cystine is proposed by the Authority. Thus, in the case of supplementation of feed and water for drinking with L-cystine as amino acid, it is appropriate to take into account the dietary supply with all essential and conditionally essential amino acids.
- (5) As regards the use as flavouring, the Authority states that no further demonstration of efficacy is necessary when used at the recommended dose. The use of L-cystine as flavouring compound is not authorised in water for drinking. At the recommended dose, L-cystine as flavouring compound is unlikely to pose any concern. The fact that the use of the L-cystine is not authorised as flavouring in water for drinking does not preclude its use in compound feed which is administered via water.
- (6) Restrictions and conditions should be provided for to allow for a better control of L-cystine as flavouring compound. For L-cystine, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures.
- (7) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2020; 18(2):6020

- (8) The assessment of L-cystine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.
- (9) 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

1. The substance L-cystine produced by *Pantoea ananatis* NITE BP-02525 specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues' is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.
2. The substance L-cystine produced by *Pantoea ananatis* NITE BP-02525 specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds' is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

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, 1 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identifica- tion number of the additive	Name of the holder of authorisa- tion	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maxi- mum age	Mini- mum content	Maxi- mum content	Other provisions	End of period of authorisation
						mg/kg of complete feed with a moisture content of 12 %			

Category: nutritional additives. Functional group: amino acids, their salts and analogues.

3c392	-	L-cystine	Additive composition: Powder with a minimum content of 98 % L-cystine	All animal species	-	-	-	1. L-cystine may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment. 4. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 5. Declaration to be made on the label of the additive and premixture: ‘ The supplementation with L-cystine, shall depend on the requirements of the target animals for sulphur- containing amino acids and the level of other sulphur-containing amino acids in the ration.	22.10.2030
			Characterisation of the active substance: L-cystine produced by fermentation with <i>Pantoea ananatis</i> NITE BP-02525 IUPAC name: (2R)-2-amino-3-[(2R)-2-amino-3-hydroxy-3-oxopropyl] disulfanyl-propanoic acid CAS number: 56-89-3 Chemical formula: C ₆ H ₁₂ N ₂ O ₄ S ₂						
			Analytical method ⁽¹⁾: For the identification of L-cystine in the feed additive: — Food Chemical Codex ‘L-cystine monograph’ For the quantification of cystine in the feed additive and premixtures: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD), as described in EN ISO 17 180 For the quantification of cystine in premixtures, compound feed and feed materials: — ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 ⁽²⁾ (Annex III, F) For the quantification of cystine in water:						

Identification number of the additive	Name of the holder of authorisation	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
						mg/kg of complete feed with a moisture content of 12 %			
			— ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), as described in EN ISO 13 903 or Commission Regulation (EC) No 152/2009 (Annex III, F)					- The supplementation with L-cystine, in particular via water for drinking, should take into account all amino acids in the animals ‘diet in order to avoid imbalances.’	

Category: Sensory additives. Functional group: Flavouring compounds

3c392	-	L-cystine	Additive composition: Powder with a minimum content of 98 % L-cystine	All animal species	-	-	-	1. L-cystine may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg.	22.10.2030
			Characterisation of the active substance: L-cystine produced by fermentation with <i>Pantoea ananatis</i> NITE BP-02525 IUPAC name: (2R)-2-amino-3-[(2R)-2-amino-3-hydroxy-3-oxopropyl] disulfanyl-propanoic acid CAS number: 56-89-3 Chemical formula: C ₆ H ₁₂ N ₂ O ₄ S ₂						
			Analytical method ⁽³⁾: For the determination of L-cystine in the feed additive: — Food Chemical Codex 'L-cystine monograph' For the quantification of cystine in the feed additive and premixtures: — ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD), as described in EN ISO 17 180						

Identification number of the additive	Name of the holder of authorisation	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
						mg/kg of complete feed with a moisture content of 12 %			
								6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. 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.	

⁽¹⁾ 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>

⁽²⁾ OJ L 54, 26.2.2009, p. 1.

⁽³⁾ 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>

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