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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.

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

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2017/959

of 24 February 2017

on the classification of horizontal settlement and short-term water absorption performance for *in situ* formed loose fill cellulose (LFCI) thermal insulation products under EN 15101-1 pursuant to Regulation (EU) No 305/2011 of the European Parliament and of the Council

(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 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC ⁽¹⁾, and in particular Article 27(1) thereof,

Whereas:

- (1) Where the Commission has not established classes of performance in relation to the essential characteristics of construction products, according to Article 27(2) of Regulation (EU) No 305/2011 they may be established by the European standardisation bodies, but only on the basis of a revised mandate.
- (2) The European product standard EN 15101-1 on *in situ* formed loose fill cellulose (LFCI) thermal insulation products contains classifications of performance concerning two of their essential characteristics, settlement for horizontal applications, lofts and floors, as well as short-term water absorption. These classifications represent a step forward for the consolidation of the internal market for the products in question.
- (3) For those new classifications, a revised mandate has not been issued.
- (4) New classification systems to be used for products covered by EN 15101-1 should therefore be established,

HAS ADOPTED THIS REGULATION:

Article 1

The performance of *in situ* formed loose fill cellulose (LFCI) thermal insulation products, in relation to their essential characteristics, settlement for horizontal applications, lofts and floors, as well as short-term water absorption, shall be classified in accordance with the classification systems set out in the Annex.

⁽¹⁾ OJ L 88, 4.4.2011, p. 5.

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, 24 February 2017.

For the Commission

The President

Jean-Claude JUNKER

ANNEX

Table 1

Classes for settlement for horizontal applications, lofts and floors

Class	
SH 0	No measureable settlement ($\leq 1 \%$)
SH 5	$\leq 5 \%$
SH 10	$\leq 10 \%$
SH 15	$\leq 15 \%$
SH 20	$\leq 20 \%$
SH 25	$\leq 25 \%$
SH 30	$> 25 \%$

Table 2

Classes of short-term water absorption

Class	
WS 1	$\leq 1,0 \text{ kg/m}^2$
WS 2	$\leq 2,0 \text{ kg/m}^2$
WS 3	$> 2,0 \text{ kg/m}^2$

COMMISSION IMPLEMENTING REGULATION (EU) 2017/960
of 2 June 2017
concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ⁽¹⁾, and in particular Articles 57(4) and 58(2) thereof,

Whereas:

- (1) In order to ensure uniform application of the Combined Nomenclature annexed to Council Regulation (EEC) No 2658/87 ⁽²⁾, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.
- (4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 34(9) of Regulation (EU) No 952/2013. That period should be set at three months.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

Article 2

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 34(9) of Regulation (EU) No 952/2013 for a period of three months from the date of entry into force of this Regulation.

Article 3

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

⁽¹⁾ OJ L 269, 10.10.2013, p. 1.

⁽²⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

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

Done at Brussels, 2 June 2017.

For the Commission,

On behalf of the President,

Stephen QUEST

Director-General

Directorate-General for Taxation and Customs Union

ANNEX

Description of goods	Classification (CN Code)	Reasons
(1)	(2)	(3)
A product in the form of a brownish, turbid extract of vanilla beans (which contains water and 35 % vol. alcohol as solvents), to which 5 % by weight of sugar has been added. The product has an intense vanilla flavour and a distinctive taste of alcohol and sugar. It is put up for retail sale in 100 ml bottles and is used to improve the taste of dishes.	2103 90 90	Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature and the wording of CN codes 2103, 2103 90 and 2103 90 90. The product cannot be considered as a vegetable extract of heading 1302 as due to the addition of sugar it has the character of a food preparation (see also the Harmonized System Explanatory Notes (HSEN) to heading 1302, point (A), sixth paragraph). Preparations used to flavour certain dishes and made from various ingredients are to be classified under heading 2103 (see also the HSEN to heading 2103, point (A), first paragraph). The product is therefore to be classified under CN code 2103 90 90 as a mixed condiment or seasoning.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/961**of 7 June 2017**

concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as a feed additive for weaned piglets, and a new use in water for drinking for weaned piglets and chickens for fattening, and amending Regulation (EC) No 2036/2005 and Regulation (EU) No 887/2011 (holder of authorisation Evonik Nutrition & Care GmbH)

(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The preparation of *Enterococcus faecium* CECT 4515 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for weaned piglets by Commission Regulation (EC) No 2036/2005 ⁽³⁾. That preparation was subsequently entered in the Register of Feed Additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003. That preparation has been authorised for chickens for fattening by Commission Implementing Regulation (EU) No 887/2011 ⁽⁴⁾.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, applications were submitted for the re-evaluation of the preparation of *Enterococcus faecium* CECT 4515 as a feed additive in feed for weaned piglets and for a new use in water for drinking for weaned piglets and chickens for fattening. The applicant requested the additive to be classified in the additive category 'zootechnical additives'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 9 April 2014 ⁽⁵⁾, 29 April 2015 ⁽⁶⁾ and 8 September 2015 ⁽⁷⁾ that, under the proposed conditions of use, the preparation of *Enterococcus faecium* CECT 4515 does not have an adverse effect on animal health, human health or the environment. In its opinion of 29 April 2015, the Authority also concluded that the additive has the potential to improve the zootechnical performance of weaned piglets when used in feed. In its opinion of 8 September 2015, the Authority further concluded that the use of the preparation of *Enterococcus faecium* CECT 4515 in water for drinking for weaned piglets and chickens for fattening has the same efficacy as when it is used in feed. 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 *Enterococcus faecium* CECT 4515 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 Annexes to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ Commission Regulation (EC) No 2036/2005 of 14 December 2005 concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of certain additives already authorised in feedingstuffs (OJ L 328, 15.12.2005, p. 13).

⁽⁴⁾ Commission Implementing Regulation (EU) No 887/2011 of 5 September 2011 concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as feed additive for chickens for fattening (holder of the authorisation Evonik Nutrition & Care GmbH) (OJ L 229, 6.9.2011, p. 7).

⁽⁵⁾ EFSA Journal 2014;12(5):3672.

⁽⁶⁾ EFSA Journal 2015;13(5):4111.

⁽⁷⁾ EFSA Journal 2015; 13(9):4232.

- (6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulation (EC) No 2036/2005 should be amended accordingly. Furthermore, the existing authorisation of the preparation of *Enterococcus faecium* CECT 4515 for chickens for fattening in Implementing Regulation (EU) No 887/2011 should be supplemented by a new use in water for drinking by way of an amendment to that Implementing Regulation.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) 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 Annex I, 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.

Article 2

Amendment to Regulation (EC) No 2036/2005

In Annex I to Regulation (EC) No 2036/2005, the entry E 1713 on *Enterococcus faecium* CECT 4515 is deleted.

Article 3

Amendment to Regulation (EU) No 887/2011

The Annex to Regulation (EU) No 887/2011 is replaced by Annex II to this Regulation.

Article 4

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 28 December 2017 in accordance with the rules applicable before 28 June 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

Entry into force

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

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

Done at Brussels, 7 June 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			

Category of zootechnical additives. Functional group: gut flora stabilisers

4b1713	Evonik Nutrition & Care GmbH)	<i>Enterococcus faecium</i> CECT 4515	<i>Additive composition</i> Preparation of <i>Enterococcus faecium</i> CECT 4515 containing a minimum of 1×10^9 CFU/g additive in solid form <i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> CECT 4515 <i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed-Field Gel Electrophoresis (PFGE)	Weaned piglets		1×10^9	—	5×10^8	—	- The additive may be used in water for drinking. - In the directions for use of the additive and premixtures stability in water for drinking shall be indicated. - In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. - For use of the additive in water for drinking a homogeneous dispersion of the additive shall be ensured. - For use in weaned piglets up to 35 kg of body weight.	28 June 2027
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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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			
										6. 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 breathing protection and skin protection.	

(¹) Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

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

4b1713	Evonik Nutrition & Care GmbH)	<i>Enterococcus faecium</i> CECT 4515	<i>Additive composition</i> Preparation of <i>Enterococcus faecium</i> CECT 4515 containing a minimum of 1×10^9 CFU/g additive Solid forms <i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> CECT 4515 <i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed-Field Gel Electrophoresis (PFGE)	Chickens for fattening	—	1×10^9	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The use is compatible in feed containing one of the following authorised coccidiostats: monensin sodium, diclazuril, nicarbazine, decoquinate, robenidine hydrochloride, semduramycin sodium, narasin, salinomycin sodium, lasalocid A sodium, narasin/nicarbazin or maduramycin ammonium. 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 breathing protection and skin protection.	26 September 2021
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

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/l of water for drinking			

Category of zootechnical additives. Functional group: gut flora stabilisers

4b1713	Evonik Nutrition & Care GmbH)	<i>Enterococcus faecium</i> CECT 4515	<i>Additive composition</i> Preparation of <i>Enterococcus faecium</i> CECT 4515 containing a minimum of 1×10^9 CFU/g additive Solid forms. <i>Characterisation of the active substance</i> Viable cells of <i>Enterococcus faecium</i> CECT 4515 <i>Analytical method</i> ⁽¹⁾ Enumeration: spread plate method using bile esculin azide agar (EN 15788) Identification: Pulsed- Field Gel Electrophoresis (PFGE)	Chickens for fattening	—	5×10^8	—	1. The additive may be used in water for drinking. 2. In the directions for use of the additive and premixtures stability in water for drinking shall be indicated. 3. For use of the additive in water for drinking a homogeneous dispersion of the additive shall be ensured. 4. The use is compatible in feed containing one of the following authorised coccidiostats: monensin sodium, diclazuril, nicarbazin, decoquinate, robenidine hydrochloride, semduramycin sodium, narasin, salinomycin sodium, lasalocid A sodium, narasin/nicarbazin or maduramycin ammonium. 5. 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 breathing protection and skin protection.	28 June 2027
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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) 2017/962**of 7 June 2017****suspending the authorisation of ethoxyquin as a feed additive for all animal species and categories****(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 13(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, denying or suspending such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The additive ethoxyquin was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use for all animal species and categories. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted on 21 September 2010 for the authorisation of ethoxyquin as a feed additive for all animal species, requesting the additive to be classified in the category 'technological additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') stated in its opinion of 21 October 2015 ⁽³⁾ that the assessment of the particulars and documents submitted by the applicant makes it impossible to conclude on the safety of the additive ethoxyquin for any target animals, for consumers and for the environment. This is due to an overall lack of data submitted to assess the exposure and the safety of ethoxyquin for animals, consumers and the environment. In particular, no conclusion is possible on the absence of genotoxicity of one of the metabolites of the additive ethoxyquin, ethoxyquin quinone imine. In addition, *p*-phenetidine, an impurity of the additive ethoxyquin, is recognised as a possible mutagen. The Authority considered the additive ethoxyquin as a potent antioxidant in feed but efficacy at the proposed use level, which has been reduced as compared with the currently authorised maximum content in feed, could not be confirmed by the submitted data. The Authority 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) Consequently, it has not been established that the additive does not have an adverse effect on animal health, human health or the environment when used under the proposed conditions.
- (6) The existing authorisation of the additive ethoxyquin therefore no longer meets the conditions set out by Article 5 of Regulation (EC) No 1831/2003.
- (7) It is possible that supplementary data concerning the safety of use and the efficacy of the additive ethoxyquin bring new elements that would allow a re-consideration of the assessment carried out for that additive. In this respect, the applicant for the authorisation of the additive ethoxyquin argues that additional studies may be performed in order to demonstrate the safety and efficacy of the additive. To this end, the applicant committed

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 270, 14.12.1970, p. 1.

⁽³⁾ EFSA Journal 2015; 13(11):4272.

itself to produce supplementary data according to a time schedule listing in order of priority the studies to be carried out successively and planning that the outcome of the last of them would be available by July 2018. The prioritisation in the process of the planned data generation is based on the level of importance of the issues identified in the Authority's opinion. Those studies would consist essentially of an update of the additive's characterisation, in particular as regards relevant impurities and degradation products, of toxicological studies, in particular related to the genotoxicity of ethoxyquin quinone imine, of metabolism and residue studies in target animal species (including levels of residues in tissues and animal products), of target animals' safety studies and of an environmental risk assessment.

- (8) In addition, as the presence in the additive ethoxyquin of the impurity *p*-phenetidine results from the manufacturing process of the additive, the applicant committed itself to take steps in order to reduce progressively the content of that impurity in the additive to the level of 2,5 ppm *p*-phenetidine in ethoxyquin by June 2017. For that purpose, an appropriate method of analysis for the detection of *p*-phenetidine in the additive ethoxyquin and in feed containing the additive should be submitted by the applicant and accepted by the Authority on the basis of a report of the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (9) In accordance with Article 13(2) of Regulation (EC) No 1831/2003, the authorisation of the additive ethoxyquin should therefore be suspended, pending the submission and assessment of the supplementary data. The suspension measure should be reviewed after due assessment of those data by the Authority. In any event, a review of the suspension measure should be adopted where, during the process of the submission and assessment of the supplementary data, the Authority adopts a non-favourable opinion on the safety or efficacy of the additive ethoxyquin.
- (10) Since further use of the additive ethoxyquin might cause a risk to human, animal health and the environment, the additive and feed containing it should be withdrawn from the market as soon as possible. For practical reasons, however, a limited transitional period should be allowed for the withdrawal from the market of the products concerned in order to enable operators to comply properly with the withdrawal obligation.
- (11) Feed materials from marine origin, which contain high levels of fatty acids, are very sensitive to oxidation and high temperature and need to be stabilised by an antioxidant, in particular where the feed materials are subject to a long shipping or storage period. Due to that high risk of oxidation, ethoxyquin is widely used to protect the feed materials concerned in an effective manner. Those feed materials, in particular fish meal and fish oil, are of high nutritional value and contain an important concentration of easily digestible proteins, which are required in aquaculture animals' and in young animals' diet, but are also used for other animal species, especially for pigs and poultry. In addition, the high content in those feed materials of poly-unsaturated fatty acids, which are transferred to animal products, is recognised to provide health benefits to livestock and to the consumers of animal products. Therefore, an immediate withdrawal from the market of ethoxyquin could lead to negative consequences for animal health and welfare and to an inability to meet the animals' specific nutritional requirements until suitable alternatives are in place.
- (12) Ethoxyquin is also widely used as constituent of certain feed additives preparations containing an active substance which is particularly sensitive to oxidation and heat treatment and needs to be stabilised by an antioxidant in order to maintain its properties. Those feed additives consist in preparations of certain essential vitamins, carotenoids and colourants which are lipo-soluble and need to be protected during the manufacturing process, storage and transport of the preparations and of feed containing them, until the delivery to animals. Due to the wide use of ethoxyquin in those feed additives preparations, an immediate withdrawal from the market of ethoxyquin would negatively impact animal health and welfare, as a result of a lack of essential micronutrients in the feed for several species of both food-producing and non-food producing animals. In addition, a shortage in the Union of the feed additives preparations concerned could lead to lower feed efficiency and lower livestock performance, but also to the inability to meet market specifications for certain animal products.
- (13) It appears that a substitution of ethoxyquin by suitable alternative antioxidants could not be undertaken immediately, as the currently authorised alternative antioxidants — several of them being still under re-evaluation process in accordance with Regulation (EC) No 1831/2003 — do not possess the same characteristics as ethoxyquin, in particular as regards effectiveness and the concentration of active substance needed, duration of action, process behaviour but also in terms of production costs. Consequently, a certain time is needed in order to allow operators to evaluate and test the functionality of alternative antioxidants through new formulations and to adapt the production process to the inclusion of those potential alternative substances. A specific definite transition period should therefore be provided for the withdrawal from the market of the products referred to in recitals 11 and 12, in order to enable operators to adapt themselves to the new situation and thereby to comply properly with the withdrawal obligation. Due to the specific method of production and storage of the feed

additives preparations mentioned under recital 12, alternative antioxidant substances for those preparations may be made available in a shorter period than for the feed materials referred to in recital 11, allowing the provision of a shorter transitional period.

- (14) 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

Suspension of the authorisation

The authorisation provided by Directive 70/524/EEC and extended by Regulation (EC) No 1831/2003, concerning the additive ethoxyquin specified in entry E 324 of the Register of feed additives referred to in Article 17 of that Regulation ('the additive ethoxyquin'), is suspended.

Article 2

Transitional measures

1. Existing stocks of the additive ethoxyquin and of premixtures containing it may continue to be placed on the market until 28 September 2017 and may be used until 28 December 2017 in accordance with the rules applicable before 28 June 2017.
2. Feed materials and compound feed produced with the additive ethoxyquin or with premixtures containing it may continue to be placed on the market until 28 December 2017 and may be used until 28 March 2018 in accordance with the rules applicable before 28 June 2017.

Article 3

Specific transitional measures for certain feed materials and related products

1. By way of derogation from Article 2:
 - (a) the additive ethoxyquin and premixtures containing it, intended to be incorporated in the feed materials listed under entry 7.1.2 and under Chapter 10 of the Catalogue of feed materials established by Commission Regulation (EU) No 68/2013 ⁽¹⁾, may continue to be placed on the market in accordance with the rules applicable before 28 June 2017 until 30 September 2019, provided that the label of the additive ethoxyquin or of premixtures containing it mentions the intended incorporation in those feed materials;
 - (b) feed materials referred to in point (a) produced with the additive ethoxyquin or with premixtures containing it may continue to be placed on the market in accordance with the rules applicable before 28 June 2017 until 31 December 2019;
 - (c) compound feed produced with the feed materials referred to in point (b) may continue to be placed on the market in accordance with the rules applicable before 28 June 2017 until 31 March 2020.

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

2. The products referred to in points (a), (b) and (c) of paragraph 1 may be used in accordance with the rules applicable before 28 June 2017 until 3 months after the dates specified respectively in those points.

Article 4

Specific transitional measures for certain additives preparations and related products

1. By way of derogation from Article 2:

(a) the additive ethoxyquin intended to be incorporated in the following additives preparations which have been authorised in accordance with Regulation (EC) No 1831/2003, may continue to be placed on the market in accordance with the rules applicable before 28 June 2017 until 31 March 2018, provided that the label of the additive ethoxyquin mentions the intended incorporation in those additives preparations:

- preparations of vitamin A;
- preparations of vitamin D;
- preparations of vitamin E;
- preparations of vitamin K;
- preparations of lutein;
- preparations of zeaxanthin;
- preparations of ethyl ester of beta-apo-8'-carotenoic acid;
- preparations of citranaxanthin;
- preparations of capsanthin;
- preparations of astaxanthin;
- preparations of astaxanthin dimethyldisuccinate;
- preparations of canthaxanthin;
- preparations of beta-carotene;

(b) the additives preparations referred to in point (a) which contain the additive ethoxyquin and premixtures containing those additives preparations may continue to be placed on the market in accordance with the rules applicable before 28 June 2017 until 30 June 2018;

(c) feed materials and compound feed containing the products referred to in point (b) may continue to be placed on the market in accordance with the rules applicable before 28 June 2017 until 30 September 2018.

2. The products referred to in points (a), (b) and (c) of paragraph 1 may be used in accordance with the rules applicable before 28 June 2017 until 3 months after the dates specified respectively in those points.

Article 5

Review

This Regulation shall be reviewed by 31 December 2020 at the latest and in any event after the adoption by the Authority of a non-favourable opinion on the safety or efficacy of the additive ethoxyquin.

*Article 6***Entry into force**

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

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

Done at Brussels, 7 June 2017.

For the Commission

The President

Jean-Claude JUNKER

COMMISSION IMPLEMENTING REGULATION (EU) 2017/963

of 7 June 2017

concerning the authorisation of the preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatinus* (formerly classified as *Aspergillus aculeatus*) (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma reesei* (formerly classified as *Trichoderma longibrachiatum*) (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP4842) and bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) as a feed additive for all avian species and weaned piglets and amending Regulations (EC) No 358/2005 and (EU) No 1270/2009 (holder of the authorisation Kemin Europa 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 Articles 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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatinus* (formerly classified as *Aspergillus aculeatus*) (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma reesei* (formerly classified as *Trichoderma longibrachiatum*) (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP4842) and bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for chickens for fattening by Commission Regulation (EC) No 358/2005 ⁽³⁾, for turkeys for fattening and weaned piglets by Commission Regulation (EU) No 1270/2009 ⁽⁴⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatinus* (formerly classified as *Aspergillus aculeatus*) (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma reesei* (formerly classified as *Trichoderma longibrachiatum*) (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP4842) and bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) as a feed additive for chickens for fattening, turkeys for fattening and for weaned piglets and, in accordance with Article 7 of that Regulation, for a new authorisation as a feed additive for all avian species. The applicant requested that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 9 September 2015 ⁽⁵⁾ that, under the proposed conditions of use, it does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the use of that preparation has the potential to be efficacious in chickens for fattening, turkeys for fattening and in laying hens ⁽⁶⁾. It was considered that those conclusions can be extended to chickens reared for laying and turkeys reared for breeding. The Authority further considered that the

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

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

⁽⁴⁾ Commission Regulation (EU) No 1270/2009 of 21 December 2009 concerning the permanent authorisations of certain additives in feedingstuffs (OJ L 339, 22.12.2009, p. 28).

⁽⁵⁾ EFSA Journal 2015; 13(9):4234.

⁽⁶⁾ Owing to lack of adequate data on enzyme recovery, the efficacy studies could not reach conclusions on efficacy at the recommended dose but were instead based on calculations and refer only to the nominal dose.

mode of action of the enzymes present in the additive can be considered to be similar in all avian species, therefore the conclusions on the efficacy in major poultry species can be extrapolated to minor poultry species and ornamental birds.

- (5) Concerning the use of the additive on weaned piglets, the Authority could not conclude on the efficacy of the additive in weaned piglets owing to lack of data. There was however a significantly higher weight gain and better feed to gain ratio than the controls in one study and in a second one, the results showed an improvement in the average daily weight gain of females, although this was not seen in males. These evidences have been judged a substantial indication of the improvement of zootechnical parameters of weight gain in addition to the long history of use. Therefore it was considered that the provided data meets the conditions for the demonstration of the efficacy of the additive for weaned piglets.
- (6) 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.
- (7) The assessment of the preparation endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatinus* (formerly classified as *Aspergillus aculeatus*) (CBS 589.94), endo-1,4-beta-glucanase produced by *Trichoderma reesei* (formerly classified as *Trichoderma longibrachiatum*) (CBS 592.94), alpha-amylase produced by *Bacillus amyloliquefaciens* (DSM 9553), endo-1,4-beta-xylanase produced by *Trichoderma viride* (NIBH FERM BP4842) and bacillolysin produced by *Bacillus amyloliquefaciens* (DSM 9554) 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.
- (8) Regulations (EC) No 358/2005 and (EU) No 1270/2009 should be amended accordingly.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (10) 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 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendments to Regulation (EC) No 358/2005

In Annex I to Regulation (EC) No 358/2005 entry E 1620 on endo-1,3(4)-beta-glucanase EC 3.2.1.6, endo-1,4-beta-glucanase EC 3.2.1.4, alpha-amylase EC 3.2.1.1, bacillolysin EC 3.4.24.28 and endo-1,4-beta-xylanase EC 3.2.1.8 is deleted.

Article 3

Amendment to Regulation (EU) No 1270/2009

Regulation (EC) No 1270/2009 is amended as follows:

- (1) Article 2 is deleted.
- (2) Annex II is deleted.

*Article 4***Transitional measures**

The preparation specified in the Annex, and feed containing that preparation, which are produced and labelled before 28 December 2017 in accordance with the rules applicable before 28 June 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

*Article 5***Entry into force**

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

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

Done at Brussels, 7 June 2017.

For the Commission

The President

Jean-Claude JUNKER

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

4a1620i	Kemin Europa NV	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-glucanase EC 3.2.1.4 Alpha-amylase EC 3.2.1.1 Endo-1,4-beta-xylanase EC 3.2.1.8 Bacillolysine EC 3.4.24.28	<i>Additive composition</i> Preparation of: — endo-1,3(4)-beta-glucanase produced by <i>Aspergillus aculeatinus</i> (formerly classified as <i>Aspergillus aculeatus</i>) (CBS 589.94), — endo-1,4-beta-glucanase produced by <i>Trichoderma reesei</i> (formerly classified as <i>Trichoderma longibrachiatum</i>) (CBS 592.94), — alpha-amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553), — endo-1,4-beta-xylanase produced by <i>Trichoderma viride</i> (NIBH FERM BP4842), — bacillolysine produced by <i>Bacillus amyloliquefaciens</i> (DSM 9554) having a minimum activity of: — Endo-1,3(4)-beta-glucanase: 2 350 U ⁽¹⁾ /g,	Chickens for fattening Chickens reared for laying Minor avian species for laying Minor avian species reared for laying Ornamental birds Piglets (weaned)	—	Endo-1,3(4)-beta-glucanase 1 175 U Endo-1,4-beta-glucanase 9 000 U Alpha-amylase 200 U Endo-1,4-beta-xylanase 17 500 U Bacillolysine 850 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 use in weaned piglets up to 35 kg of body weight. 3. 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 and skin protection. 4. Recommended use level in laying hens: endo-1,3(4)-beta-glucanase: 1 175 U; endo-1,4-beta-glucanase: 9 000 U; alpha-amylase: 200 U; endo-1,4-beta-xylanase: 17 500 U; bacillolysine: 850 U/kg of complete feed.	28 June 2027
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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 %			
			— Endo-1,4-beta-glucanase: 18 000 U ⁽²⁾/g, — alpha-amylase: 400 U ⁽³⁾/g, — Endo-1,4-beta-xylanase: 35 000 U ⁽⁴⁾/g, — bacillolysin 1 700 U ⁽⁵⁾/g Solid form Characterisation of the active substance — endo-1,3(4)-beta-glucanase produced by <i>Aspergillus aculeatinus</i> (CBS 589.94), — endo-1,4-beta-glucanase produced by <i>Trichoderma reesei</i> (CBS 592.94), — alpha-amylase produced by <i>Bacillus amyloliquefaciens</i> (DSM 9553), — endo-1,4-beta-xylanase produced by <i>Trichoderma viride</i> (NIBH FERM BP4842), — bacillolysin produced by <i>Bacillus amyloliquefaciens</i> (DSM 9554).						

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 %			
			<i>Analytical method</i> ⁽⁶⁾ For the determination in feed additive of: — endo-1,3(4)-beta-glucanase in the feed additives: colorimetric method based on the enzymatic hydrolysis of glucanase on the barley beta-glucan substrate at pH 7,5 and 30 °C, — endo-1,4-beta-glucanase in the feed additives: colorimetric method based on the enzymatic hydrolysis of cellulase on the carboxymethylcellulose at pH 4,8 and 50 °C, — alpha-amylase in the feed additives: colorimetric method based on the formation of water soluble dyed fragments produced by the action of amylase on azurine cross-linked starch polymer substrates at pH 7,5 and 37 °C, — endo-1,4-beta-xylanase in the feed additives: colorimetric method based on the enzymatic hydrolysis of xylanase on the birchwood xylane substrate at pH 5,3 and 50 °C,	All Turkeys Laying hens Minor avian species for fattening		Endo-1,3(4) beta-glucanase 588 U Endo-1,4-beta-glucanase 4 500 U Alpha-amylase 100 U Endo-1,4-beta-xylanase 8 750 U Bacillolysin 425 U			

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 %			
			— bacillolysin: colorimetric method based on the release of azo-dye resulting from the action of protease on the azo-casein substrate at pH 7,5 and 37 °C. For the determination in pre-mixtures and feedingstuffs of: — endo-1,3(4)-beta-glucanase: plate test method based on the glucanase diffusion and the subsequent decolouring of the red agar medium due to the beta-glucan hydrolysis, — endo-1,4-beta-glucanase: colorimetric method based on the quantification of the water soluble dye fragments produced by the action of cellulase on azurine cross-linked water insoluble HE-cellulose substrate, — alpha-amylase: colorimetric method based on the formation of water soluble blue fragments produced by the action of amylase on azurine cross-linked insoluble blue-coloured starch polymer substrates,						

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 %			
			— endo-1,4-beta-xylanase: colorimetric method based on the quantification of water soluble dyed fragments produced by the action of xylanase on azurine cross-linked wheat arabinoxylan, — bacillolysin: test plate method based on the diffusion of protease in the azo-casein agar medium and the subsequent hydrolysis of casein.						

(¹) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 7,5 and 30 °C.

(²) 1 U is the amount of enzyme which liberates 0,0056 micromoles of reducing sugars (glucose equivalents) from carboxymethylcellulose per minute at pH 4,8 and 50 °C.

(³) 1 U is the amount of enzyme which hydrolyses 1 micromole of glycosidic linkages from water insoluble cross-linked starch polymer per minute at pH 7,5 and 37 °C.

(⁴) 1 U is the amount of enzyme which liberates 0,0067 micromoles of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 5,3 and 50 °C.

(⁵) 1 U is the amount of enzyme which solubilises one microgram of azo-casein substrate per minute at pH 7,5 and 37 °C.

(⁶) 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>

CORRIGENDA**Corrigendum to Council Decision (Euratom) 2017/956 of 29 May 2017 on the adoption of the 2016-2019 high flux reactor supplementary research programme to be implemented by the Joint Research Centre for the European Atomic Energy Community**

(Official Journal of the European Union L 144 of 7 June 2017)

On page 24, in the signatory:

for: 'C. CORDONA',

read: 'C. CARDONA'.

Corrigendum to Council Regulation (EC) No 1801/2006 of 30 November 2006 on the conclusion of the Fisheries Partnership Agreement between the European Community and the Islamic Republic of Mauritania

(Official Journal of the European Union L 343 of 8 December 2006)

On page 3, in Article 4, footnote 2:

for: '(2) Plus the sum of the contributions to be paid by shipowners as provided for in Chapter III of Annex I, paid directly to Mauritania into the account provided for in Chapter IV of Annex I, which is estimated at EUR 22 million per year.',

read: '(2) The date of entry into force of the Agreement will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.'.

