

Official Journal

of the European Union

L 73

English edition

Legislation

Volume 50
13 March 2007

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I Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory

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⁽¹⁾ Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 242/2007

of 6 March 2007

concerning the authorisation of endo-1,4-beta xylanase EC 3.2.1.8 (Belfeed B1100MP and Belfeed B1100ML) as a feed additive

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 set out in the Annex. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns a new use of the preparation of endo-1,4-beta xylanase EC 3.2.1.8 produced by *Bacillus subtilis* (LMG S-15136), as a feed additive for ducks, to be classified in the additive category 'zootechnical additives'.
- (4) The method of analysis included in the application for authorisation in accordance with Article 7(3)(c) of

Regulation (EC) No 1831/2003 concerns the determination of the active substance of the feed additive in feed. The method of analysis referred to in the Annex to this Regulation is therefore not to be understood as a Community method of analysis within the meaning of Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ⁽²⁾.

- (5) The use of endo-1,4-beta xylanase EC 3.2.1.8 produced by *Bacillus subtilis* (LMG S-15136) was authorised without a time limit for piglets (weaned) by Commission Regulation (EC) No 1206/2005 ⁽³⁾ and for chickens for fattening by Commission Regulation (EC) No 1259/2004 ⁽⁴⁾. New data were submitted in support of an application for authorisation for ducks. The European Food Safety Authority (the Authority) concluded in its opinion of 15 June 2006 ⁽⁵⁾ that the safety of this additive for the consumer, the user and the environment have already been established and will not be changed by the proposed new use. It further concluded, that the use of the preparation does not have an adverse effect on this additional animal category and that the use of that preparation can improve the zootechnical parameters in ducks. 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

⁽¹⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽²⁾ OJ L 165, 30.4.2004, p. 1; corrected by OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OL L 363, 20.12.2006, p. 1).

⁽³⁾ OJ L 197, 28.7.2005, p. 12.

⁽⁴⁾ OJ L 239, 9.7.2004, p. 8.

⁽⁵⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the enzyme preparation Belfeed B1100MP and belfeed B1100ML (endo-1-4-beta xylanase) authorised as a feed additive in accordance with Council Directive 70/524/EEC. Adopted on 15 June 2006. The EFSA Journal (2006) 368, 1.

Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

HAS ADOPTED THIS REGULATION:

Article 1

- (6) The assessment of that preparation shows that the conditions for authorisation, 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.

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

- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

This Regulation shall enter into force on the 20th day following 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, 6 March 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (trade name)	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.									
4a1606	Beldem SA	endo-1,4-beta-xylanase EC 3.2.1.8 (Belfeed B1100MP Belfeed B1100ML)	Additive composition Preparation of endo-1,4-beta- xylanase EC 3.2.1.8 having a minimum of activity solid and liquid form 100 IU ⁽¹⁾ /g or ml Characterisation of the active substance endo-1,4-beta-xylanase EC 3.2.1.8 produced by <i>Bacillus subtilis</i> (LMG S-15136) Analytical method ⁽²⁾ Colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate	Ducks	—	10 IU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuffs: endo-1,4-beta-xylanase: 10 IU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat. 4. If the product is handled or mixed in a confined atmosphere, it is recommended to use safety glasses and masks for mixing if the mixers are not equipped with exhaust systems.	2.4.2017

⁽¹⁾ One IU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4,5 and 30 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/

COMMISSION REGULATION (EC) No 243/2007**of 6 March 2007****concerning the authorisation of 3-phytase (Natuphos) as a feed additive****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 set out in the Annex. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns authorisation of the enzyme preparation 3-phytase produced by *Aspergillus niger* (CBS 101.672) for weaned piglets, pigs for fattening, and chickens for fattening to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority (the Authority) concluded in its opinions of 15 June 2006 and of 17 May 2006 that 3-phytase produced by *Aspergillus niger* (CBS 101.672) does not have an adverse effect on animal health, human health or the environment ⁽²⁾. It further

concluded that the enzyme preparation 3-phytase produced by *Aspergillus niger* (CBS 101.672) does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. The opinion of the Authority recommends appropriate measures for user safety. It does not consider that there is a need for specific requirements of post market monitoring. This opinion also verifies the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003. The assessment of that preparation shows that the conditions for authorisation, 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.

- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

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 20th day following 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, 6 March 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OL 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽²⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed and of the Scientific Panel on Genetically Modified Organisms on the safety and efficacy of the enzyme preparation Natuphos® (3-phytase) produced by *Aspergillus niger*. Adopted by FEEDAP Panel on 15 June 2006 and by the GMO Panel on 17 May 2006. *The EFSA Journal* (2006) 369, p. 1.

ANNEX

Identi-fication number of the additive	Name of the holder of authorisation	Additive (trade name)	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.									
4a 1600	BASF Aktienge-sellschaft	3-phytase EC 3.1.3.8 (Natuphos 5 000 G Natuphos 5 000 L Natuphos 10 000 G Natuphos 10 000 L)	Additive composition 3-phytase produced by <i>Aspergillus niger</i> (CBS 101.672) having a minimum activity of: Solid form: 5 000 FTU/g Liquid form: 5 000 FTU/ml Characterisation of the active sub-stance 3-phytase produced by <i>Aspergillus niger</i> (CBS 101.672) Analytical method ⁽¹⁾ Colorimetric method measuring inor-ganic phosphate released by the enzyme from phytate substrate.	Piglets (weaned)	—	500 FTU		1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For use in weaned piglets up to 35 kg. 3. Recommended dose per kilo-gram of complete feedingstuff: 500 FTU. 4. For use in feed containing more than 0,23 % phytin bound phos-phorus.	2.4.2017
				Pigs for fat-tening		280 FTU		1. In the direction of use of the additive and premixtures, indi-cate the storage life and stability in pelleting. 2. Recommended dose per kilo-gram of complete feedingstuff: 400500 FTU. 3. For use in feed containing more than 0,23 % phytin bound phosphorus.	
				Chickens for fattening	—	375 FTU		1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dose per kilo-gram of complete feedingstuff: 500700 FTU. 3. For use in feed containing more than 0,23 % phytin bound phosphorus.	

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlfaa/

COMMISSION REGULATION (EC) No 244/2007**of 7 March 2007****concerning the authorisation of L-histidine monohydrochloride monohydrate as a feed additive****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) An application for authorisation has been submitted for L-histidine monohydrochloride monohydrate as an amino acid.
- (3) As the application for authorisation was submitted before the date of application of Regulation (EC) No 1831/2003, it was submitted under Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ⁽²⁾. As from 18 October 2004, amino acids, their salts and analogues fall under the scope of Regulation (EC) No 1831/2003. The application is therefore to be considered as an application under Article 7 of Regulation (EC) No 1831/2003.
- (4) In order to comply with the requirements laid down in Article 7 of Regulation (EC) No 1831/2003, additional information was submitted in support of the application.
- (5) The application concerns authorisation of L-histidine monohydrochloride monohydrate as a feed additive for salmonids, to be classified in the additive category 'nutritional additives' and the functional group 'amino acids, their salts and analogues'.

- (6) The European Food Safety Authority (the Authority) concluded in its opinions of 2 March 2005 ⁽³⁾ and of 18 October 2006 ⁽⁴⁾ that L-histidine monohydrochloride monohydrate does not have an adverse effect on animal health, human health or the environment. It further concluded that L-histidine monohydrochloride monohydrate does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. According to that opinion, it is an essential amino acid also for fish, and the use of that preparation has been shown to prevent cataracts under farming conditions for salmonids. The opinion of the Authority recommends appropriate measures for user safety. It does not consider that there is a need for specific requirements of post market monitoring. The report on the method of analysis of the feed additive in feed was submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003 to the Authority. The assessment of that preparation shows that the conditions for authorisation, 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation 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 20th day following its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽²⁾ OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).

⁽³⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and the bioavailability of product L-Histidine monohydrochloride monohydrate for salmonids. Adopted on 2 March 2005. *The EFSA Journal* (2005) 195, p. 1.

⁽⁴⁾ Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed under Regulation (EC) 1831/2003 on L-Histidine monohydrochloride monohydrate as feed additive for use in salmonids. Adopted on 18 October 2006. *The EFSA Journal* (2006) 407, p. 1.

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

Done at Brussels, 7 March 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

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
						Maximum content in mg/kg of complete feedingstuff			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c3.5.1	—	L-histidine mono-hydrochloride monohydrate	Characterisation of the additive L-histidine monohydrochloride monohydrate 98 % produced by <i>Escherichia coli</i> (ATCC 9637) C ₃ H ₃ N ₂ -CH ₂ -CH(NH ₂)-COOH· HCl· H ₂ O Analytical method Community method for the determination of aminoacids (Commission Directive 98/64/EC amending Directive 71/393/EEC ⁽¹⁾)	Salmonids	—	—	—	—	2.4.2017

⁽¹⁾ OJ L 257, 19.9.1998, p. 14

COMMISSION REGULATION (EC) No 245/2007

of 8 March 2007

amending and adapting Annex II to Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards Bulgaria, Romania and Malaysia

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Treaty of Accession of Bulgaria and Romania, and in particular Article 4(3) thereof,

Having regard to the Act of Accession of Bulgaria and Romania, and in particular Article 56 thereof,

Having regard to Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC ⁽¹⁾, and in particular Articles 10 and 19 thereof,

Whereas:

- (1) Regulation (EC) No 998/2003 lays down the animal health requirements applicable to the non-commercial movement of pet animals and the rules applicable to checks on such movements.
- (2) Regulation (EC) No 998/2003 lays down that a list of third countries from which the movement of pet animals to the Community may be authorised, provided that certain requirements are met, is to be set out in Part C of Annex II to that Regulation.
- (3) The list in Part C of Annex II to Regulation (EC) No 998/2003 includes third countries and territories which are free of rabies and third countries and territories in respect of which the risk of rabies entering the Community as a result of movements from those third countries and territories has been found to be no higher than the risk associated with movements between Member States.
- (4) From the information submitted by the competent authorities of Malaysia, it appears that the risk of rabies

entering the Community as a result of movements of pet animals from that country is no higher than the risk associated with movements of pet animals between Member States or from third countries already listed in Regulation (EC) No 998/2003. Therefore Malaysia should be included in the list set out in Part C of Annex II to Regulation (EC) No 998/2003.

- (5) Since Bulgaria and Romania have been Member States since 1 January 2007, in the interest of clarity of Community legislation it is necessary to remove references to those countries from Part C of Annex II to Regulation (EC) No 998/2003 with effect from the date of accession.
- (6) Regulation (EC) No 998/2003 should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In Regulation (EC) No 998/2003 Part C of Annex II is amended as follows:

- (1) The following entries are deleted:
‘BG — Bulgaria
RO — Romania’.
- (2) The following entry is inserted: ‘MY — Malaysia’.

*Article 2*This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

Article 1(1) shall apply from 1 January 2007.

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

Done at Brussels, 8 March 2007.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 146, 13.6.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 1467/2006 (OJ L 274, 5.10.2006, p. 3).

DIRECTIVES

COMMISSION DIRECTIVE 2007/13/EC

of 7 March 2007

amending Annex II to Council Directive 71/316/EEC on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 71/316/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control⁽¹⁾, and in particular the first sentence of Article 16 thereof,

Whereas:

- (1) Directive 71/316/EEC makes provision, in item 3.1.1.1(a) of Annex II, for the distinguishing capital letters of Member States to be used for the EEC initial verification mark affixed on a measuring instrument and indicating that the latter conforms to the EEC requirements.
- (2) Directive 71/316/EEC makes provision, in item 3.2.1 of Annex II, for the drawings, showing the shape, dimensions and outline of the letters for the EEC initial verification marks as laid down in item 3.1 of that Annex.
- (3) The drawings of the distinguishing letters were not provided in the Act of Accession of Austria, Finland and Sweden and in the 2003 Act of Accession. According to Annex II, Chapter 1, point D1.b of the Act of Accession of Austria, Finland and Sweden, and of the 2003 Act of Accession, the drawings to which Annex II item 3.2.1 of Directive 71/316/EEC refers are supplemented by the requisite letters.
- (4) It is therefore necessary to amend item 3.2.1 of Annex II to Directive 71/316/EEC in order to include the drawings of the distinguishing letters.
- (5) The measures provided for in this Directive are in accordance with the opinion of the Committee for Adjustment to Technical Progress set up under Article 17 of Directive 71/316/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 71/316/EEC is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 10 March 2008 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 7 March 2007.

For the Commission

Günter VERHEUGEN

Vice-President

⁽¹⁾ OJ L 202, 6.9.1971, p. 1. Directive as last amended by the 2003 Act of Accession.

ANNEX

In the first drawing attached to Annex II to Directive 71/316/EEC the letters 'A, S, Fl, CZ, EST, CY, LV, LT, H, M, PL, Sl, SK' are supplemented by the following drawings:

