Official Journal of the European Union

L 231

English edition

Legislation

Volume 58

4 September 2015

Contents

[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.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1489

of 3 September 2015

concerning the authorisation of the preparation of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237 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. Article 10(7) of Regulation (EC) No 1831/2003 in conjunction with Article 10(1) to (4) thereof sets out specific provisions for the evaluation of products used in the Union as silage additives.

(2) In accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003, the preparations of *Lactobacillus plantarum* MBS-LP-01 (NCIMB 30238) and of *Pediococcus pentosaceus* MBS-PP-01 (NCIMB 30237) were entered in the Register of Feed Additives as existing products belonging to the functional group of silage additives, for all animal species.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, two applications were submitted for the authorisation of the preparations as feed additives for all animal species, requesting the additives to be classified in the category 'technological additives' and in the functional group 'silage additives'. These 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 23 May 2012 ([2]), and 11 September 2014 ([3]) that, under the proposed conditions of use, the preparations concerned do not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the mixture of the preparations of *Pediococcus pentosaceus* NCIMB 30237 and *Lactobacillus plantarum* NCIMB 30238, when used in a ratio of 8:2, has the potential to improve the preservation of nutrients in silage prepared from easy, moderately difficult and difficult to ensile material. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2012; 10(6):2732 and 2733.
([3]) EFSA Journal 2014; 12(9):3829.

(5) Two applications were evaluated separately for safety and efficacy, but the Authority concluded that the efficacy was only demonstrated by the mixture in well precise ratio of both. Therefore it is proposed to authorise only one preparation. The assessment of the preparation of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237 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 preparation should be authorised as specified in the Annex to this Regulation.

(6) 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.

(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

Authorisation

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

Article 2

Transitional measures

The preparation specified in the Annex and feed containing it, which are produced and labelled before 24 March 2016 in accordance with the rules applicable before 24 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 3 September 2015.

For the Commission
The President
Jean-Claude JUNCKER

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
						CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives									
1k21008	—	*Lactobacillus plantarum* NCIMB 30238 *Pediococcus pentosaceus* NCIMB 30237	*Additive composition* Preparation of *Lactobacillus plantarum* NCIMB 30238 containing a minimum of $2,0 \times 10^{10}$ CFU/g additive and *Pediococcus pentosaceus* NCIMB 30237 containing a minimum of $2,6 \times 10^{10}$ CFU/g additive. *Characterisation of the active substance* Viable cells of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237. *Analytical method* (1) Enumeration in the feed additive of *Lactobacillus plantarum* NCIMB 30238: spread plate method using MRS agar (EN 15787). Identification of *Lactobacillus plantarum* NCIMB 30238: Pulsed Field Gel Electrophoresis (PFGE). Enumeration in the feed additive *Pediococcus pentosaceus* NCIMB 30237: spread plate method (EN 15786) Identification of *Pediococcus pentosaceus* NCIMB 30237: pulsed field gel electrophoresis (PFGE).	All animal species	—	—	—	1. In the directions for use of the additive and premixture, indicate the storage conditions. 2. Minimum content of *Lactobacillus plantarum* NCIMB 30238 and *Pediococcus pentosaceus* NCIMB 30237: 1×10^8 CFU (ratio 1:4) per kg fresh material. 3. For safety: it is recommended to use breathing protection, eye protection and gloves during handling.	24 September 2025

(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) 2015/1490

of 3 September 2015

concerning the authorisation of the preparation of carvacrol, cinnamaldehyde and capsicum oleoresin as a feed additive for chickens for fattening (holder of the authorisation Pancosma France S.A.S.)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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 carvacrol, cinnamaldehyde and capsicum oleoresin. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation of carvacrol, cinnamaldehyde and capsicum oleoresin as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2015 ([2]) that, under the proposed conditions of use, the preparation of carvacrol, cinnamaldehyde and capsicum oleoresin does not have an adverse effect on animal health, human health or the environment, and that it has a potential to improve the feed to gain ratio in chickens for fattening. 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 carvacrol, cinnamaldehyde and capsicum oleoresin 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.

Article 2

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2015;13(2):4011.

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

Done at Brussels, 3 September 2015.

For the Commission
The President
Jean-Claude JUNCKER

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/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical parameters)									
4d11	Pancosma France S.A.S.	Preparation of carvacrol, cinnamaldehyde and capsicum oleoresin	*Additive composition* Preparation of carvacrol, cinnamaldehyde, capsicum oleoresin having a content of: — carvacrol 4,6 %-5,3 % — capsicum oleoresin ≥ 2 % (with a content of the sum of capsaicin and dihydrocapsaicin 0,06 %-0,21 %) — cinnamaldehyde 2,6 %-3,2 % *Characterisation of the active substances* — carvacrol (1) (≥ 98 % purity) $C_{10}H_{14}O$ CAS number: 499-75-2 — cinnamaldehyde (1) (≥ 98 % purity) C_9H_8O CAS number: 104-55-2 — capsicum oleoresin with a minimum content of the sum of capsaicin and dihydrocapsaicin 6 %-7 % *Analytical method* (2) For the quantification of carvacrol, cinnamaldehyde, capsaicin and dihydrocapsaicin in the feed additive: — Gas Chromatography with Flame Ionisation Detection (GC-FID)	Chickens for fattening	—	—	100	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. The additive shall not be used with other sources of carvacrol, cinnamaldehyde, capsaicin and dihydrocapsaicin. 3. For safety: breathing protection, glasses and gloves shall be used during handling. 4. Minimum recommended dose: 100 mg/kg of complete feedingstuff.	24 September 2025

(1) JECFA, Online Edition: 'Specifications for Flavourings'. http://www.fao.org/ag/agn/jecfa-flav/index.html#T
(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) 2015/1491

of 3 September 2015

amending Regulation (EU) No 37/2010 as regards the substance 'virginiamycin'

(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ([1]), and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit (hereinafter 'MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is established in a regulation.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Virginiamycin is not yet included in this table.

(4) An application for the establishment of MRLs for virginiamycin in chicken has been submitted to the European Medicines Agency (hereinafter 'EMA').

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended the establishment of a MRL for virginiamycin in chicken, applicable to muscle, skin and fat, liver and kidney, provided that the substance is not used for animals from which eggs are produced for human consumption.

(6) According to Article 5 of Regulation (EC) No 470/2009 the EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

(7) The EMA has considered that the extrapolation of the MRL for virginiamycin from chicken to poultry is appropriate.

(8) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(9) It is appropriate to grant the stakeholders concerned a reasonable period of time to take measures that may be required to comply with the new MRL.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

([1]) OJ L 152, 16.6.2009, p. 11.
([2]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

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

It shall apply from 3 November 2015.

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

Done at Brussels, 3 September 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, an entry for the following substance is inserted in alphabetical order:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Virginiamycin	Virginiamycin factor S1	Poultry	10 µg/kg	Muscle	Not for use in animals from which eggs are produced for human consumption	Anti-infectious agents/ Antibiotics'
			30 µg/kg	Skin and fat		
			10 µg/kg	Liver		
			60 µg/kg	Kidney		

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1492

of 3 September 2015

amending Regulation (EU) No 37/2010 as regards the substance 'tylvalosin'

(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]), and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit (hereinafter 'MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is established in a regulation.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Tylvalosin is currently included in that table as an allowed substance, for porcine and poultry species, applicable to muscle, skin and fat, liver and kidney in porcine species and to skin and fat and liver in poultry species, excluding animals producing eggs for human consumption.

(4) An application for the extension of the existing entry for tylvalosin to chicken eggs has been submitted to the European Medicines Agency (hereinafter 'EMA').

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use has recommended the establishment of a MRL for chicken eggs.

(6) According to Article 5 of Regulation (EC) No 470/2009 the EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

(7) The EMA has considered that the extrapolation of the MRLs for tylvalosin from chicken eggs to eggs of other poultry species is appropriate.

(8) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(9) It is appropriate to grant the stakeholders concerned a reasonable period of time to take measures that may be required to comply with the new MRL.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

([1]) OJ L 152, 16.6.2009, p. 11.
([2]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in the Annex to this Regulation.

Article 2

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

It shall apply from 3 November 2015.

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

Done at Brussels, 3 September 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, the entry for the substance 'tylvalosin' is replaced by the following:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic classification
'Tylvalosin	Tylvalosin	Porcine	50 µg/kg	Muscle	NO ENTRY	Anti-infectious agents/Antibiotics'
			50 µg/kg	Skin and fat		
			50 µg/kg	Liver		
			50 µg/kg	Kidney		
		Poultry	200 µg/kg	Eggs		
	Sum of Tylvalosin and 3-0-acetyltylosin	Poultry	50 µg/kg	Skin and fat		
			50 µg/kg	Liver		

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1493

of 3 September 2015

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

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

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

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 3 September 2015.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	MA	175,1
	MK	41,5
	XS	34,4
	ZZ	83,7
0707 00 05	TR	116,3
	ZZ	116,3
0709 93 10	TR	116,3
	ZZ	116,3
0805 50 10	AR	137,9
	BO	147,4
	CL	131,9
	UY	133,8
	ZA	133,7
	ZZ	136,9
0806 10 10	BA	74,4
	EG	243,0
	MA	201,0
	MK	63,9
	TR	136,2
	ZZ	143,7
0808 10 80	AR	119,1
	BR	99,5
	CL	135,5
	NZ	123,8
	US	168,2
	UY	110,5
	ZA	112,3
	ZZ	124,1
0808 30 90	AR	87,1
	CL	110,6
	CN	88,6
	TR	133,4
	ZA	113,1
	ZZ	106,6
0809 30 10, 0809 30 90	MK	68,9
	TR	147,4
	ZZ	108,2

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0809 40 05	BA	57,0
	IL	336,8
	MK	47,2
	XS	70,3
	ZZ	127,8

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

CORRIGENDA

Corrigendum to Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC

(Official Journal of the European Union L 293 of 5 November 2013)

On page 12, in Article 15(3):

for: '… authorities designated in accordance with points (a) and (c) of paragraph 1 …';

read: '… authorities designated in accordance with points (a) and (b) of paragraph 1 …'.

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

Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

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