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⁽⁴⁾ Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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⁽⁶⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/148

of 3 February 2020

concerning the authorisation of robenidine hydrochloride (Robenz 66G) as a feed additive for chickens for fattening and amending Regulation (EC) No 1800/2004 (holder of authorisation Zoetis SA)

(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(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The preparation of robenidine hydrochloride (Robenz 66G) was authorised, in accordance with Directive 70/524/EEC, as a feed additive for chickens for fattening by Commission Regulation (EC) No 1800/2004 ⁽³⁾. 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 thereof, an application was submitted for the re-evaluation of robenidine hydrochloride (Robenz 66G) as a feed additive for chickens for fattening. The applicant requested that additive to be classified in the additive category 'coccidiostats and histomonostats'. 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 24 January 2019 ⁽⁴⁾ that, under the proposed conditions of use, robenidine hydrochloride (Robenz 66G) does not have an adverse effect on animal health, human health or the environment. The Authority considered that the additive has the potential to effectively control coccidiosis in chickens for fattening. The Authority considered that there is a need for a field post-market monitoring of *Eimeria* spp., preferably during the latter part of the period of the authorisation. 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 robenidine hydrochloride (Robenz 66G) 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.

⁽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 1800/2004 of 15 October 2004 concerning the authorisation for 10 years of the additive Cycostat 66G in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances (OJ L 317, 16.10.2004, p. 37).

⁽⁴⁾ EFSA Journal 2019; 17(3):5613.

- (6) As a consequence of this re-evaluation, Regulation (EC) No 1800/2004 should be amended accordingly.
- (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

The preparation specified in the Annex, belonging to the additive category 'coccidiostats and histomonostats', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 1800/2004 is amended as follows:

- (1) Article 2 is deleted;
- (2) the Annex is deleted.

Article 3

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 25 August 2020 in accordance with the rules applicable before 25 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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 February 2020.

For the Commission

The President

Ursula VON DER LEYEN

Identification number of additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
Additive category: Coccidiostats and histomonostats										
5a758	Zoetis SA	Robenidine hydrochloride (Robenz 66G)	Additive composition: Robenidine hydrochloride: 66 g/kg Lignosulfonate: 40 g/kg Calcium sulfate dihydrate: 894 g/kg Active substance: Robenidine hydrochloride, C ₁₅ H ₁₃ Cl ₂ N ₅ HCl, 1,3-bis[(p-chlorobenzylidene) amino]-guanidine hydrochloride (97 %) CAS number: 25875-50-7, Related impurities: — N,N',N"-tris[(p-chlorobenzylidene) amino]guanidine (TRIS) ≤ 0,5 % — bis-(4-chlorobenzylidene) hydrazine (AZIN) ≤ 0,5 % — unknown impurity ≤ 1 % (individual unknown impurity ≤ 0,2 %) Analytical method ⁽¹⁾ For the quantification of robenidine hydrochloride in the feed additive and premixtures: High Performance Liquid Chromatography coupled to Ultraviolet detection (HPLC-UV) For the quantification of robenidine hydrochloride in fee-	Chickens for fattening	—	36	36	1. Use of the additive prohibited at least five days before slaughter. 2. The additive shall be incorporated in compound feed in the form of a premixture. 3. The additive shall not be mixed with other coccidiostats. 4. Post-market monitoring programmes shall be carried out by the holder of authorisation for: resistance to bacteria and <i>Eimeria</i> spp. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks of 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.	25 February 2030	800 µg robenidine hydrochloride/kg of wet liver. 350 µg robenidine hydrochloride/kg of wet kidney. 200 µg robenidine hydrochloride/kg of wet muscle. 1300 µg robenidine hydrochloride/kg of wet skin/fat.

Identifi- cation number of additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description	Species or category of animal	Maxi- mum age	Mini- mum content	Maxi- mum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			dingstuffs: High Performance Liquid Chromatography coupled to Ultraviolet detec- tion (HPLC-UV) – Commission Regulation (EC) No 152/2009 For the quantification of robe- nidine hydrochloride in tis- sues: Reversed-Phase High Per- formance Liquid Chromatography coupled to a triple quadrupole mass spec- trometer (RP-HPLC-MS/MS) or any equivalent methods complying with the require- ments set by Commission De- cision 2002/657/EC.							

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

COMMISSION IMPLEMENTING REGULATION (EU) 2020/149**of 4 February 2020****concerning the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for lambs and horses and repealing Regulations (EC) No 1293/2008 and (EC) No 910/2009 (holder of authorisation Danstar Ferment AG represented in the Union by Lallemand SAS)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) *Saccharomyces cerevisiae* CNCM I-1077 was authorised for 10 years as a feed additive for lambs by Commission Regulation (EC) No 1293/2008 ⁽²⁾ and as a feed additive for horses by Commission Regulation (EC) No 910/2009 ⁽³⁾.
- (3) An application was submitted by the holder of that authorisation for the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for lambs and horses, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 February 2019 ⁽⁴⁾ that the applicant has provided data demonstrating that the additive complies with the conditions for authorisation. The Authority concluded that *Saccharomyces cerevisiae* CNCM I-1077 remains safe under the authorised conditions of use for the target animals, consumers, users and the environment. The Authority also concluded that the additive is considered an eyes irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (5) The assessment of *Saccharomyces cerevisiae* CNCM I-1077 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1293/2008 and (EC) No 910/2009 should be repealed.
- (7) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to provide for a transitional period during which the existing stocks of the preparation of *Saccharomyces cerevisiae* CNCM I-1077, which are in conformity with the provisions applying before the date of entry into force of this Regulation, may continue to be placed on the market and used until they are exhausted.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 1293/2008 of 18 December 2008 concerning the authorisation of a new use of *Saccharomyces cerevisiae* CNCM I-1077 (Levucell SC20 and Levucell SC10 ME) as a feed additive (OJ L 340, 19.12.2008, p. 38).

⁽³⁾ Commission Regulation (EC) No 910/2009 of 29 September 2009 concerning the authorisation of a new use of the preparation of *Saccharomyces cerevisiae* CNCM I-1077 as a feed additive for horses (holder of authorisation Danstar Ferment AG represented in the Union by Lallemand SAS) (OJ L 257, 30.9.2009, p. 7).

⁽⁴⁾ EFSA Journal 2019;17(3):5639.

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional groups 'gut flora stabilisers' for lambs and 'digestibility enhancers' for horses, is renewed subject to the conditions laid down in that Annex.

Article 2

Regulations (EC) No 1293/2008 and (EC) No 910/2009 are repealed.

Article 3

Saccharomyces cerevisiae CNCM I-1077, as set out in Regulation (EC) No 910/2009, premixtures and compound feed containing that substance, which are produced and labelled before 25 February 2020 in accordance with the rules applicable before 25 February 2020 may continue to be placed on the market and used until the existing stock are exhausted.

Article 4

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, 4 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4b1711	Danstar Ferment AG represented by Lallemand SAS	<i>Saccharomyces cerevisiae</i> CNCM I-1077	<i>Additive composition:</i> Preparation of <i>Saccharomyces cerevisiae</i> CNCMI-1077 containing a minimum of: — 1 × 10 ¹⁰ CFU/g of additive (coated form); — 2 × 10 ¹⁰ CFU/g of additive (not-coated form); <i>Characterisation of the active substance</i> Viable cells of <i>Saccharomyces cerevisiae</i> CNCM I-1077 <i>Analytical method</i> ⁽¹⁾ Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN15789:2009) Identification: polymerase chain reaction (PCR) method (CEN/TS 15790:2008)	Horses	-	3,0 × 10 ⁹	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye protection.	25.2.2030

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1711	Danstar Ferment AG represented by Lallemand SAS	<i>Saccharomyces cerevisiae</i> CNCM I-1077	<i>Additive composition</i> Preparation of <i>Saccharomyces cerevisiae</i> CNCM I-1077 containing a minimum of: — 1 × 10 ¹⁰ CFU/g of additive (coated form); — 2 × 10 ¹⁰ CFU/g of additive (not-coated form); <i>Characterisation of the active substance</i> Viable cells of <i>Saccharomyces cerevisiae</i> CNCM I-1077 <i>Analytical method</i> ⁽¹⁾ Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN15789:2009) Identification: polymerase chain reaction (PCR) method (CEN/TS 15790:2008)	Lambs	-	3,0 × 10 ⁹		1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye protection.	25.2.2030

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

COMMISSION IMPLEMENTING REGULATION (EU) 2020/150**of 4 February 2020**

concerning the authorisation of the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056 as a feed additive for chickens for fattening, chickens reared for laying and for breeding and minor poultry species for fattening or reared for laying or for breeding purposes (holder of authorisation Andrés Pintaluba S.A.)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns the authorisation of a preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening or reared for laying or for breeding purposes to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 ⁽²⁾ that, under the proposed conditions of use, the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive may have respiratory sensitisation potential. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. It concluded that the additive has the potential to improve the utilisation of the phosphorus. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of 6-phytase produced by *Komagataella phaffii* CGMCC 12056 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2019; 17(4):5692.

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, 4 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a31	Andrés Pinaluba S.A.	6-phytase EC 3.1.3.26	Additive composition Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Komagataella phaffii</i> CGMCC 12056, having a minimum activity of: Solid form: 20 000 U ⁽¹⁾ /g Liquid form: 20 000 U/ml	Chickens for fattening	-	250 U		1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	25 February 2030
			Characterisation of the active substance 6-phytase produced by <i>Komagataella phaffii</i> CGMCC 12056	Chickens reared for laying and breeding					
			Analytical method ⁽²⁾ For the quantification of phytase activity in the feed additive: colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.4; For the quantification of phytase activity in premixtures: colorimetric method based on the enzymatic reaction of phytase on the phytate – VDLUFA 27.1.3; For the quantification of phytase activity in feedingstuffs: colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024.	Minor poultry species for fattening or reared for laying or for breeding purposes					

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

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

COMMISSION IMPLEMENTING REGULATION (EU) 2020/151

of 4 February 2020

concerning the authorisation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for all porcine species for fattening and for breeding other than sows, all avian species, all fish species and all crustaceans and repealing Regulations (EC) No 911/2009, (EU) No 1120/2010 and (EU) No 212/2011 and Implementing Regulations (EU) No 95/2013, (EU) No 413/2013 and (EU) 2017/2299 (holder of authorisation Danstar Ferment AG represented in the Union by Lallemand SAS)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) *Pediococcus acidilactici* CNCM I-4622 (former *Pediococcus acidilactici* CNCM MA 18/5M) was authorised for 10 years as a feed additive for salmonids and shrimps by Commission Regulation (EC) No 911/2009 ⁽²⁾, for weaned piglets by Commission Regulation (EU) No 1120/2010 ⁽³⁾, for laying hens by Commission Regulation (EU) No 212/2011 ⁽⁴⁾, for all fish other than salmonids by Commission Implementing Regulation (EU) No 95/2013 ⁽⁵⁾, for weaned piglets, pigs for fattening, laying hens and chickens for fattening by Commission Implementing Regulation (EU) No 413/2013 ⁽⁶⁾, for pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, minor poultry species for fattening and minor poultry species for laying by Commission Implementing Regulation (EU) 2017/2299 ⁽⁷⁾.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of the authorisation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive for the renewal of the authorisation for chickens for fattening, minor avian species for fattening, laying hens, minor avian species for laying, weaned piglets, pigs for fattening, minor porcine species (weaned) and for fattening, all fish and shrimp, and for a new authorisation for chickens reared for laying and for breeding purposes, for ornamental birds and other non-food producing birds, for turkeys for fattening, for turkeys reared for breeding purposes, for turkeys for breeding purposes, for chickens for breeding purposes and related minor poultry species and other ornamental and non-food producing birds, for suckling piglets and related minor porcine species, for all crustaceans, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Articles 7(3) and 14(2) of that Regulation

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 911/2009 of 29 September 2009 concerning the authorisation of a new use of the preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for salmonids and shrimps (holder of authorisation Danstar Ferment AG) (OJ L 257, 30.9.2009, p. 10).

⁽³⁾ Commission Regulation (EU) No 1120/2010 of 2 December 2010 concerning the authorisation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for weaned piglets (holder of the authorisation Danstar Ferment AG) (OJ L 317, 3.12.2010, p. 12).

⁽⁴⁾ Commission Regulation (EU) No 212/2011 of 3 March 2011 concerning the authorisation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for laying hens (holder of authorisation Danstar Ferment AG) (OJ L 59, 4.3.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 95/2013 of 1 February 2013 concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for all fish other than salmonids (holder of authorisation Danstar Ferment AG) (OJ L 33, 2.2.2013, p. 19).

⁽⁶⁾ Commission Implementing Regulation (EU) No 413/2013 of 6 May 2013 concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for use in water for drinking for weaned piglets, pigs for fattening, laying hens and chickens for fattening (holder of authorisation Danstar Ferment AG) (OJ L 125, 7.5.2013, p. 1).

⁽⁷⁾ Commission Implementing Regulation (EU) 2017/2299 of 12 December 2017 concerning the authorisation of a preparation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for pigs for fattening, minor porcine species (weaned and for fattening), chickens for fattening, minor poultry species for fattening and minor poultry species for laying, the authorisation of that feed additive for use in water for drinking and amending Regulations (EC) No 2036/2005, (EC) No 1200/2005 and Implementing Regulation (EU) No 413/2013 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (OJ L 329, 13.12.2017, p. 33).

- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 2 April 2019 ⁽⁸⁾ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority confirmed its previous conclusions that *Pediococcus acidilactici* CNCM I-4622 is considered safe for the target species, consumers of products from animals fed with the additive and the environment. It also concluded that there is a potential for users to be exposed via inhalation and that no conclusion could be drawn on the potential for skin and eyes irritancy and dermal sensitisation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. It also concluded that the additive is efficacious for chickens reared for laying, chickens reared for breeding, chickens for breeding, turkeys and minor avian species reared for laying/breeding and for breeding, and for suckling piglets and minor porcine species for breeding and for fattening and all crustaceans.
- (5) The assessment of *Pediococcus acidilactici* CNCM I-4622 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of *Pediococcus acidilactici* CNCM I-4622 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 911/2009, (EU) No 1120/2010 and (EU) No 212/2011 and Implementing Regulations (EU) No 95/2013, (EU) No 413/2013 and (EU) 2017/2299 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' for all porcine species for fattening and for breeding other than sows, all birds, and to the functional group 'other zootechnical additives' for all fish and all crustaceans is renewed subject to the conditions laid down in that Annex.

Article 2

Regulations (EC) No 911/2009, (EU) No 1120/2010 and (EU) No 212/2011, as well as Implementing Regulations (EU) No 95/2013, (EU) No 413/2013 and (EU) 2017/2299 are repealed.

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*.

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

Done at Brussels, 4 February 2020.

For the Commission

The President

Ursula VON DER LEYEN

⁽⁸⁾ EFSA Journal 2019;17(4):5691 and EFSA Journal 2019;17(5):5690.

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	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

4d1712	Danstar Ferment AG represented in the Union by Lallemand SAS	<i>Pediococcus acidilactici</i> CNCM I-4622	Additive composition Preparation of <i>Pediococcus acidilactici</i> CNCM I-4622 containing a minimum of 1×10^{10} CFU/g	All porcine species for fattening and for breeding, other than sows	-	1×10^9	-	5×10^8	-	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 of the additive in water for drinking the homogenous dispersion of the additive shall be ensured. 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.	25 February 2030
			Solid not-coated and coated forms								
			Characterisation of the active substance Viable cells of <i>Pediococcus acidilactici</i> CNCM I-4622								
			Analytical method ⁽¹⁾ Enumeration of the active substance in feed additive, premixtures, feedingstuffs and water: spread plate method using MRS agar (EN 15786:2009). Identification: Pulsed Field Gel Electrophoresis (PFGE) method.	All avian species							

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: other zootechnical additives (favourably affect growth)											
4d1712	Danstar Ferment AG represented in the Union by Lallemand SAS	Pediococcus acidilactici CNCM I-4622	Additive composition Preparation of <i>Pediococcus acidilactici</i> CNCM I-4622 containing a minimum of 1 × 10 ¹⁰ CFU/g	All fish species	-	1 x 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 additive shall only be used in solid feed. 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.	
			Characterisation of the active substance Viable cells of <i>Pediococcus acidilactici</i> CNCM I-4622	All crustaceans							
			Analytical method Enumeration of the active substance in feed additive, premixtures, feedingstuffs and water: spread plate method using MRS agar (EN 15786:2009). Identification: Pulsed Field Gel Electrophoresis (PFGE) method.								

(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>

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/152

of 3 February 2020

prohibiting Romania to repeat granting authorisations under Article 53(1) of Regulation (EC) No 1107/2009 for the plant protection products containing the active substance clothianidin or imidacloprid for use on *Brassica napus* against *Phyllotreta* spp. or *Psylliodes* spp.

(notified under document C(2020) 458)

(Only the Romanian text is authentic)

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 53(3)(a) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 485/2013 ⁽²⁾ amended the conditions of approval of the active substances thiamethoxam, clothianidin and imidacloprid, belonging to the class of neonicotinoids. Article 2 of that Regulation prohibited the sale and use of seeds of certain crops treated with plant protection products containing these active substances, with the exception of seeds used in greenhouses. Accordingly, Member States had to amend or withdraw existing authorisations for plant protection products containing those active substances.
- (2) Since 28 February 2014 Romania has repeatedly granted emergency authorisations covering the treatment of seeds, sale and sowing of seeds treated with plant protection products containing those active substances, based on the derogation provided for in Article 53(1) of Regulation (EC) No 1107/2009 for emergency situations. These emergency authorisations were duly notified to the Commission and to the other Member States.
- (3) On 20 March 2017, Romania notified the Commission four emergency authorisations in force from 1 February 2017 until 16 May 2017 for plant protection products containing the active substances imidacloprid (NUPRID AL 600 FS and Seedoprid 600 FS), thiamethoxam (Cruiser 350 FS) and clothianidin (PONCHO 600 FS) for use on both *Helianthus annuus* and *Zea mays* against *Agriotes* spp. and *Tanymecus dilaticollis*. On 13 September 2017, Romania notified the Commission two emergency authorisations in force from 21 July 2017 to 16 October 2017 for plant protection products containing the active substances imidacloprid (NUPRID AL 600 FS) and clothianidin (MODESTO 480 FS) for use on *Brassica napus* against *Phyllotreta* spp. and *Psylliodes* spp.
- (4) On 15 September 2017, in accordance with Article 53(2) of Regulation (EC) No 1107/2009, the Commission asked the European Food Safety Authority ('the Authority') to assess several Member States', including Romania's, emergency authorisations for plant protection products containing the active substances clothianidin, imidacloprid and thiametoxam for uses no longer approved by Implementing Regulation (EU) No 485/2013, in the light of the conditions for emergency authorisations laid down in Article 53(1) of Regulation (EC) No 1107/2009.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiametoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (OJ L 139, 25.5.2013, p. 12).

- (5) On 18 May 2018, Romania again notified emergency authorisations for plant protection products MODESTO 480 FS and NUPRID AL 600 FS, containing the active substances clothianidin and imidacloprid for seed treatment and sowing of treated seeds, for use on *Brassica napus* var. *napobrassica* against *Phyllotreta* spp. and *Psylliodes* spp.
- (6) In respect of the three active substances concerned, Commission Implementing Regulations (EU) 2018/783 ⁽³⁾, (EU) 2018/784 ⁽⁴⁾ and (EU) 2018/785 ⁽⁵⁾ confirmed the restrictions imposed by Implementing Regulation (EU) No 485/2013. They further restricted the use of plant protection products containing the active substances imidacloprid, clothianidin and thiamethoxam allowing only for authorisation of uses as insecticides in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses. Furthermore, resulting crops must stay within permanent greenhouses during their entire life cycle.
- (7) In the technical report prepared upon Commission's request referred to in recital 4 and published on 21 June 2018 ⁽⁶⁾ regarding the six crop/pest combinations, for which the emergency authorisation were given by Romania, the Authority concluded that for three crop/pest combinations there was a product containing an alternative active substance authorised with the same mode of action, namely, *Brassica napus*/*Phyllotreta atra.*, *Brassica napus*/*Psylliodes chrysocephala*, and *Zea mays*/*Tanymecus dilaticollis*. Yet, four products did not only cover *Zea mays*/*Tanymecus dilaticollis*, for which an alternative existed, but were used at the same time to cover other crop/pest combinations, namely *Zea mays*/*Agriotes* spp., *Helianthus annuus*/*Agriotes* spp. and *Helianthus annuus*/*Tanymecus dilaticollis*, for which no product containing an alternative substance was available.
- (8) Therefore, based on the assessment by the Authority, the Commission considers that the conditions laid down in Article 53(1) of Regulation (EC) No 1107/2009 were not met in Romania in respect of authorisations for MODESTO 480 FS containing the active substance clothianidin and for NUPRID AL 600 FS containing the active substance imidacloprid for use for the crop/pest combinations *Brassica napus*/*Phyllotreta* spp. and *Brassica napus*/*Psylliodes* spp. as these emergency authorisations cover a crop/pest combination for which another product, containing an alternative active substance with the same mode of action, was authorised. The products covering *Zea mays*/*Tanymecus dilaticollis*, for which another product, containing an alternative active substance with the same mode of action, was authorised also covered another pest for the same crop for which no alternative was available, and, consequently the Commission considers the use of these products acceptable on *Zea mays*, as usage of multiple plant protection products on the same crop to address different pests should not be encouraged when avoidable.
- (9) Accordingly, by letter of 16 July 2018 the Commission requested Romania to confirm that it would not repeat the granting of emergency authorisations for the plant protection products MODESTO 480 FS containing the active substance clothianidin and NUPRID AL 600 FS containing the active substance imidacloprid for use on the crop/pest combinations *Brassica napus*/*Phyllotreta* spp. and *Brassica napus*/*Psylliodes* spp. In its reply of 18 September 2018, Romania took the view that the respective emergency authorisations were justified.
- (10) The Commission considers it necessary to decide that Romania may not repeat the granting of emergency authorisations for plant protection products, containing the active substance clothianidin and/or imidacloprid, for use on the crop/pest combinations *Brassica napus*/*Phyllotreta* spp., or *Brassica napus*/*Psylliodes* spp.
- (11) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Romania may not repeat the granting of authorisation under Article 53(1) of Regulation (EC) No 1107/2009 for plant protection products containing the active substances clothianidin or imidacloprid for use on *Brassica napus* against the pests *Phyllotreta* spp. or *Psylliodes* spp.

⁽³⁾ Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (OJ L 132, 30.5.2018, p. 31).

⁽⁴⁾ Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ L 132, 30.5.2018, p. 35).

⁽⁵⁾ Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (OJ L 132, 30.5.2018, p. 40).

⁽⁶⁾ EFSA Supporting Publications 2018:EN-1416.

Article 2

This decision is addressed to Romania.

Done at Brussels, 3 February 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2020/153

of 3 February 2020

prohibiting Lithuania to repeat granting authorisations under Article 53(1) of Regulation (EC) No 1107/2009 for the plant protection products containing the active substance thiamethoxam for use on spring rape against *Phyllotreta* spp. and/or *Psylliodes* spp.

*(notified under document C(2020) 464)***(Only the Lithuanian text is authentic)****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 53(3)(a) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 485/2013 ⁽²⁾ amended the conditions of approval of the active substances thiamethoxam, clothianidin and imidacloprid, belonging to the class of neonicotinoids. Article 2 of that Regulation prohibited the sale and use of seeds of certain crops treated with plant protection products containing these active substances, with the exception of seeds used in greenhouses. Accordingly, Member States had to amend or withdraw existing authorisations for plant protection products containing those active substances.
- (2) Since 26 February 2016, Lithuania has repeatedly granted emergency authorisations covering the treatment of seeds, sale and sowing of seeds treated with plant protection products containing those active substances, based on the derogation provided for in Article 53(1) of Regulation (EC) No 1107/2009 for emergency situations. These emergency authorisations were duly notified to the Commission and to the other Member States.
- (3) On 3 March 2017, Lithuania notified the Commission two emergency authorisations in force from 1 March 2017 until 28 June 2017 for a plant protection product containing thiamethoxam (CRUISER OSR) for use on spring rape against *Phyllotreta nemorum* and *Psylliodes chrysocephala* and for a plant protection product containing clothianidin (MODESTO) for the use on spring rape against *Athalia rosae*, *Delia radicum*, *Phyllotreta* spp. and *Psylliodes* spp..
- (4) On 15 September 2017, in accordance with Article 53(2) of Regulation (EC) No 1107/2009, the Commission asked the European Food Safety Authority ('the Authority') to assess several Member States', including Lithuania's, emergency authorisations for plant protection products containing the active substances clothianidin, imidacloprid and thiametoxam for uses no longer approved by Implementing Regulation (EU) No 485/2013, in the light of the conditions for emergency authorisations laid down in Article 53(1) of Regulation (EC) No 1107/2009.
- (5) On 1 March 2018, Lithuania again notified an emergency authorisation for the product CRUISER OSR containing the active substance thiamethoxam for seed treatment and sowing of treated seeds, for use on spring rape against *Phyllotreta nemorum* and *Psylliodes chrysocephala*.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiametoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (OJ L 139, 25.5.2013, p. 12).

- (6) In respect of the three active substances concerned, Commission Implementing Regulations (EU) 2018/783 ⁽³⁾, (EU) 2018/784 ⁽⁴⁾ and (EU) 2018/785 ⁽⁵⁾ confirmed the restrictions imposed by Implementing Regulation (EU) No 485/2013. They further restricted the use of plant protection products containing the active substances imidacloprid, clothianidin and thiamethoxam allowing only for authorisation of uses as insecticides in permanent greenhouses or for the treatment of seeds intended to be used only in permanent greenhouses. Furthermore, resulting crops must stay within permanent greenhouses during their entire life cycle.
- (7) In the technical report prepared upon Commission's request referred to in recital 4 and published on 21 June 2018 ⁽⁶⁾ regarding the four crop/pest combinations, for which the emergency authorisation were given by Lithuania, the Authority concluded that for two crop/pest combinations there was a product containing an alternative active substance authorised with the same mode of action, namely, spring rape/*Phyllotreta* spp. and spring rape/*Psylliodes* spp.. Yet, one product did not only cover spring rape/*Phyllotreta* spp. and spring rape/*Psylliodes* spp., for which an alternative existed, but was used at the same time to cover other crop/pest combinations, namely spring rape/*Athalia rosae* and spring rape/*Delia radicum*, for which no product containing an alternative substance was available.
- (8) Therefore, based on the assessment by the Authority, the Commission considers that the conditions laid down in Article 53(1) of Regulation (EC) No 1107/2009 were not met in Lithuania as regards CRUISER OSR, containing the active substance thiamethoxam for use for the crop/pest combinations spring rape/*Phyllotreta* spp. and spring rape/*Psylliodes* spp. as these emergency authorisations contain a crop/pest combination for which another product, containing an alternative active substance with the same mode of action, was authorised. The product covering spring rape/*Athalia rosae* and spring rape/*Delia radicum*, for which another product, containing an alternative active substance with the same mode of action, was authorised also covered another pest for the same crop for which no alternative was available, and, consequently the Commission considers the use of this product acceptable on spring rape as usage of multiple plant protection products on the same crop to address different pests should not be encouraged when avoidable.
- (9) Accordingly, by letter of 16 July 2018 the Commission requested Lithuania to confirm that it would not repeat the granting of emergency authorisations for the plant protection product CRUISER OSR containing the active substance thiamethoxam for use on the crop/pest combinations spring rape/*Phyllotreta* spp. and spring rape/*Psylliodes* spp. In its reply of 17 September 2018, Lithuania informed that it considered the emergency authorisation justified.
- (10) The Commission considers it necessary to decide that Lithuania may not repeat the granting of emergency authorisations for plant protection products, containing the active substance clothianidin or thiamethoxam, for use on the crop/pest combinations spring rape/*Phyllotreta* spp. and spring rape/*Psylliodes* spp..
- (11) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Lithuania may not repeat the granting of authorisation under Article 53(1) of Regulation (EC) No 1107/2009 for plant protection products containing the active substance thiamethoxam for use on spring rape against the pests *Phyllotreta* spp. or *Psylliodes* spp..

⁽³⁾ Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (OJ L 132, 30.5.2018, p. 31).

⁽⁴⁾ Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ L 132, 30.5.2018, p. 35).

⁽⁵⁾ Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (OJ L 132, 30.5.2018, p. 40).

⁽⁶⁾ EFSA supporting publication 2018:EN-1421.

Article 2

This decision is addressed to the Republic of Lithuania.

Done at Brussels, 3 February 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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