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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736, *Pediococcus acidilactici* CNCM I-3237, *Pediococcus acidilactici* DSM 11673/CNCM I-4622, *Pediococcus pentosaceus* NCIMB 12455, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-4323 and *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus buchneri* CNCM I-4323/ NCIMB 40788 as feed additives for all animal species, amending Implementing Regulations (EU) No 1065/2012, (EU) No 1119/2012, (EU) No 1113/2013 and (EU) No 304/2014 and repealing Implementing Regulations (EU) No 990/2012 and (EU) No 2019/764

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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concerning the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736, *Pediococcus acidilactici* CNCM I-3237, *Pediococcus acidilactici* DSM 11673/CNCM I-4622, *Pediococcus pentosaceus* NCIMB 12455, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-4323 and *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus buchneri* CNCM I-4323/ NCIMB 40788 as feed additives for all animal species, amending Implementing Regulations (EU) No 1065/2012, (EU) No 1119/2012, (EU) No 1113/2013 and (EU) No 304/2014 and repealing Implementing Regulations (EU) No 990/2012 and (EU) No 2019/764

(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) The preparations of *Lactiplantibacillus plantarum* (previously taxonomically identified as *Lactobacillus plantarum*) CNCM I-3235 and of *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736 (previously taxonomically identified as *Lactobacillus plantarum* CNCM MA 18/5U) were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 1065/2012[2].

(3) The preparation of *Pediococcus acidilactici* CNCM I-3237 was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 304/2014[3].

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1 OJ L 268, 18.10.2003, p. 29.

2 Commission Implementing Regulation (EU) No 1065/2012 of 13 November 2012 concerning the authorisation of preparations of *Lactobacillus plantarum* (DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944) as feed additives for all animal species (OJ L 314, 14.11.2012, p. 15).

3 Commission Implementing Regulation (EU) No 304/2014 of 25 March 2014 concerning the authorisation of the preparations of *Enterococcus faecium* NCIMB 10415, *Enterococcus faecium* DSM 22502 and *Pediococcus acidilactici* CNCM I-3237 as feed additives for all animal species (OJ L 90, 26.3.2014, p. 8).

(4) The preparations of *Pediococcus acidilactici* DSM 11673/CNCM I-4622 (previously taxonomically identified as *Pediococcus acidilactici* CNCM MA 18/5M - DSM 11673) and of *Pediococcus pentosaceus* NCIMB 12455 were authorised for a period of 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 1119/2012[4].

(5) The preparation of *Acidipropionibacterium acidipropionici* CNCM I-4661 (previously taxonomically identified as *Propionibacterium acidipropionici* CNCM MA 26/4U) was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 990/2012[5].

(6) The preparation of *Lentilactobacillus buchneri* (previously taxonomically identified as *Lactobacillus buchneri*) NCIMB 40788/ CNCM I-4323 was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 1113/2013[6].

(7) The preparation of *Lentilactobacillus hilgardii* (previously taxonomically identified as *Lactobacillus hilgardii*) CNCM I-4785 and *Lentilactobacillus buchneri* (previously taxonomically identified as *Lactobacillus buchneri*) CNCM I-4323/ NCIMB 40788 was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 2019/764[7].

(8) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736, *Pediococcus acidilactici* CNCM I-3237, *Pediococcus acidilactici* DSM 11673/CNCM I-4622, *Pediococcus pentosaceus* NCIMB 12455, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus. buchneri* NCIMB 40788/ CNCM I-4323 and *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus. buchneri* CNCM I-4323/ NCIMB 40788 as feed additives for all animal species, requesting the additives to be classified in the additive category 'technological additives' and in the functional group 'silage additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(9) The European Food Safety Authority ('the Authority') concluded in its opinion of 31 January 2023[8] that the above mentioned preparations remain safe for all animal species, the consumers and the environment under the existing conditions of

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4 Commission Implementing Regulation (EU) No 1119/2012 of 29 November 2012 concerning the authorisation of preparations of *Pediococcus acidilactici* CNCM MA 18/5M DSM 11673, *Pediococcus pentosaceus* DSM 23376, NCIMB 12455 and NCIMB 30168, *Lactobacillus plantarum* DSM 3676 and DSM 3677 and *Lactobacillus buchneri* DSM 13573 as feed additives for all animal species (OJ L 330, 30.11.2012, p. 14).

5 Commission Implementing Regulation (EU) No 990/2012 of 25 October 2012 concerning the authorisation of a preparation of *Propionibacterium acidipropionici* (CNCM MA 26/4U) as a feed additive for all animal species (OJ L 297, 26.10.2012, p. 15).

6 Commission Implementing Regulation (EU) No 1113/2013 of 7 November 2013 concerning the authorisation of preparations of *Lactobacillus plantarum* NCIMB 40027, *Lactobacillus buchneri* DSM 22501, *Lactobacillus buchneri* NCIMB 40788/CNCM I-4323, *Lactobacillus buchneri* LN 40177/ATCC PTA-6138, and *Lactobacillus buchneri* LN 4637/ATCC PTA-2494 as feed additives for all animal species (OJ L 298, 8.11.2013, p. 29).

7 Commission Implementing Regulation (EU) No 2019/764 of 14 May 2019 concerning the authorisation of a preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/NCIMB 40788 as a feed additive for all animal species (OJ L 126, 15.5.2019, p. 1).

8 EFSA Journal 2023;21(2):7865.

authorisation. It also concluded that the additives should be considered as respiratory sensitisers. In the absence of data, no conclusions could be drawn on the skin sensitisation, and skin and eye irritancy potential of the additives, with the exception for *Pediococcus acidilactici* DSM 11673/CNCM I-4622 that is considered non-irritant to skin and eyes. It also indicated that there is no need for assessing the efficacy of the additives in the context of the renewal of the authorisation.

(10) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessments carried out regarding the method of analysis of the preparations of *Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736, *Pediococcus acidilactici* CNCM I-3237, *Pediococcus acidilactici* DSM 11673/CNCM I-4622, *Pediococcus pentosaceus* NCIMB 12455, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus. buchneri* NCIMB 40788/ CNCM I-4323 and *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus. buchneri* CNCM I-4323/ NCIMB 40788 as feed additives in the context of the previous authorisations are valid and applicable for the current application. In accordance with Article 5(4), point (c) of Commission Regulation (EC) No 378/2005[9], an evaluation report of the Reference Laboratory is therefore not required.

(11) In view of the above, the Commission considers that the preparations of *Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736, *Pediococcus acidilactici* CNCM I-3237, *Pediococcus acidilactici* DSM 11673/CNCM I-4622, *Pediococcus pentosaceus* NCIMB 12455, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-4323 and *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus. buchneri* CNCM I-4323/ NCIMB 40788 satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of those additives should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(12) As a consequence of the renewal of the authorisation of the preparations of *Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736, *Pediococcus acidilactici* CNCM I-3237, *Pediococcus acidilactici* DSM 11673/CNCM I-4622, *Pediococcus pentosaceus* NCIMB 12455, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-4323 and *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus buchneri* CNCM I-4323/ NCIMB 40788 as feed additives, Implementing Regulations (EU) No 1065/2012, (EU) No 1119/2012, (EU) No 1113/2013 and (EU) No 304/2014 should be amended and Implementing Regulations (EU) No 990/2012 and (EU) No 2019/764 should be repealed.

(13) Since safety reasons do not require the immediate application of the modifications to the conditions of the authorisation of the preparations of *Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736, *Pediococcus acidilactici* DSM 11673/CNCM I-4622, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-

[9] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

4323 and *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus buchneri* CNCM I-4323/ NCIMB 40788, in relation to the taxonomical change of the microorganisms contained therein, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisations.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1
Renewal of authorisation

The authorisation of the preparations specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, are renewed subject to the conditions laid down in that Annex.

Article 2
Amendment to Implementing Regulation (EU) No 1065/2012

In the Annex to Implementing Regulation (EU) No 1065/2012, entry 1k20717 on *Lactobacillus plantarum* (CNCM I-3235) and entry 1k20722 on *Lactobacillus plantarum* (CNCM MA 18/5U) are deleted.

Article 3
Amendment to Implementing Regulation (EU) No 1119/2012

In the Annex to Implementing Regulation (EU) No 1119/2012, entry 1k2104 on *Pediococcus acidilactici* DSM 11673/CNCM I-4622 and entry 1k2106 on *Pediococcus pentosaceus* NCIMB 12455 are deleted.

Article 4

Amendment to Implementing Regulation (EU) No 1113/2013

In the Annex to Implementing Regulation (EU) No 1113/2013, entry 1k20739 on *Lactobacillus buchneri* NCIMB 40788/CNCM I-4323 is deleted.

Article 5
Amendment to Implementing Regulation (EU) No 304/2014

In the Annex to Implementing Regulation (EU) No 304/2014, entry 1k21009 on *Pediococcus acidilactici* CNCM I-3237 is deleted.

Article 6
Repeal of Implementing Regulations (EU) No 990/2012 and (EU) No 2019/764

Implementing Regulations (EU) No 990/2012 and (EU) No 2019/764 are repealed.

Article 7
Transitional measures

The preparations of *Lactiplantibacillus plantarum* CNCM I-3235, *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736, *Pediococcus acidilactici* DSM 11673/CNCM I-4622, *Acidipropionibacterium acidipropionici* CNCM I-4661, *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-4323 and *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus buchneri* CNCM I-4323/ NCIMB 40788 specified in the Annex, and feed containing them which are produced and labelled before [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.

Article 8
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,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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								
1k20717	*Lactiplantibacillus plantarum* CNCM I-3235	**Additive composition** Preparation of *Lactiplantibacillus plantarum* CNCM I-3235 containing a minimum of 5 x 10^{10} CFU/g additive --- **Characterisation of the active substance** Viable cells of *Lactiplantibacillus plantarum* CNCM I-3235 **Analytical method**[1] - Enumeration: Spread plate method: EN 15787 - Identification: Pulsed- Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other microorganisms as silage additives: 2 x 10^7 CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[1] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
							skin, eye and breathing protective equipment.	

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
1k20722	*Lactiplantibacillus. plantarum* DSM 11672/ CNCM I-3736	**Additive composition** Preparation of *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736 containing a minimum of 2 x 10^{10} CFU/g additive --- **Characterisation of the active substance** Viable cells of *Lactiplantibacillus plantarum* DSM 11672/ CNCM I-3736 **Analytical method**[2] - Enumeration: Spread plate method: EN 15787 - Identification: Pulsed- Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other microorganisms as silage additives: 1 x 10^8 CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[2] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
1k21009	*Pediococcus acidilactici* CNCM I-3237	**Additive composition** Preparation of *Pediococcus acidilactici* CNCM I-3237 containing a minimum of 1x 10^{10} CFU/g additive --- **Characterisation of the active substance** Viable cells of *Pediococcus acidilactici* CNCM I-3237 **Analytical method**[3] - Enumeration: Spread plate method: EN 15786 - Identification: Pulsed- Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other microorganisms as silage additives: 5 x 10^7 CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*
1k2104	*Pediococcus acidilactici* DSM 11673/CNCM I-4622	**Additive composition**	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the	*[10 years from the date of entry into*

[3] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
		Preparation of *Pediococcus acidilactici* DSM 11673/CNCM I-4622 containing a minimum of 3 x 10^9 CFU/g additive . --- **Characterisation of the active substance** Viable cells of *Pediococcus. acidilactici* DSM 11673/CNCM I-4622 **Analytical method**[4] - Enumeration: Spread plate method: EN 15786 - Identification: Pulsed- Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods					storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other microorganisms as silage additives: 3 x 10^7 CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment.	*force of this Regulation. To be completed by the OP]*

[4] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
1k2106	*Pediococcus pentosaceus* NCIMB 12455	**Additive composition** Preparation of *Pediococcus pentosaceus* NCIMB 12455 containing a minimum of 3 x10^9 CFU/g additive ---------- **Characterisation of the active substance** Viable cells of *Pediococcus pentosaceus* NCIMB 12455 **Analytical method**[5] - Enumeration: Spread plate method: EN 15786 - Identification: Pulsed- Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other microorganisms as silage additives: 3 x 10^7 CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[5] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
1k2111	*Acidipropionibacterium acidipropionici* CNCM I-4661	**Additive composition** Preparation of *Acidipropionibacterium acidipropionici* CNCM I-4661 containing a minimum of 1 x 10^8 CFU/g additive ---------- **Characterisation of the active substance** Viable cells of *Acidipropionibacterium acidipropionici* CNCM I-4661 **Analytical method**[6] - Enumeration: Spread plate method: EN 15787 - Identification: Pulsed- Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other microorganisms as silage additives: 1 x 10^8 CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[6] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
1k20739	*Lentilactobacillus. buchneri* NCIMB 40788/ CNCM I-4323	**Additive composition** Preparation of *Lentilactobacillus buchneri* NCIMB 40788/CNCM I-4323 containing a minimum of 3 x 10^9 CFU/g additive --- **Characterisation of the active substance** Viable cells of *Lentilactobacillus buchneri* NCIMB 40788/ CNCM I-4323 **Analytical method**[7] - Enumeration: Spread plate method: EN 15787 - Identification: Pulsed- Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1 x 10^8 CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[7] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

Identification number of the additive	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								
1k20757	*Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus. buchneri* CNCM I-4323/ NCIMB 40788	**Additive composition** Preparation of *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus buchneri* CNCM I-4323/NCIMB 40788 containing a minimum of 1.5 x 10^{11} CFU/g additive (ratio of 1:1) --- **Characterisation of the active substance** Viable cells of *Lentilactobacillus hilgardii* CNCM I-4785 and *Lentilactobacillus buchneri* CNCM I-4323/ NCIMB 40788 **Analytical method**[8] - Enumeration: Spread plate method: EN 15787 - Identification: Pulsed- Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing methods	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 3 × 10^8 CFU/kg (*L. hilgardii* CNCM I-4785 and *L. buchneri* CNCM I-4323/NCIMB 40788 in ratio of 1:1) of easy and moderately difficult to ensile fresh material[9]. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

8 Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

9 Easy to ensile forage: > 3 % soluble carbohydrates in fresh material. Moderately difficult to ensile forage: 1,5-3,0 % soluble carbohydrates in the fresh material. Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1)

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category of technological additives. Functional group: silage additives								
							such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Lactiplantibacillus plantarum* DSM 23375 as a feed additive for all animal species and amending Implementing Regulation (EU) No 1065/2012

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Lactiplantibacillus plantarum* DSM 23375 as a feed additive for all animal species and amending Implementing Regulation (EU) No 1065/2012

(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) The preparation of *Lactiplantibacillus plantarum* DSM 23375 (previously taxonomically identified as *Lactobacillus plantarum* DSM 23375) was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 1065/2012[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Lactiplantibacillus plantarum* DSM 23375 as a feed additive for all animal species, requesting the additive to be classified in the additive category ‘technological additives’ and in the functional group ‘silage additives’. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 12 May 2023[3] that the preparation of *Lactiplantibacillus plantarum* DSM 23375 remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is not irritant to skin or eyes but that, owing to its proteinaceous nature, it should be considered a respiratory sensitiser. The Authority could not conclude on the skin sensitisation potential of the

[1] OJ L 268, 18.10.2003, p. 29.

[2] Commission Implementing Regulation (EU) No 1065/2012 of 13 November 2012 concerning the authorisation of preparations of *Lactobacillus plantarum* (DSM 23375, CNCM I-3235, DSM 19457, DSM 16565, DSM 16568, LMG 21295, CNCM MA 18/5U, NCIMB 30094, VTT E-78076, ATCC PTSA-6139, DSM 18112, DSM 18113, DSM 18114, ATCC 55943 and ATCC 55944) as feed additives for all animal species (OJ L 314, 14.11.2012, p. 15*)*.

[3] EFSA Journal 2023;21(6):8054.

additive. It also indicated that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparation of *Lactiplantibacillus plantarum* DSM 23375 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005[4], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that the preparation of *Lactiplantibacillus plantarum* DSM 23375 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) As a consequence of the renewal of the authorisation of the preparation of *Lactiplantibacillus plantarum* DSM 23375 as a feed additive, Implementing Regulation (EU) No 1065/2012 should be amended accordingly.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of *Lactiplantibacillus plantarum* DSM 23375, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) No 1065/2012

In the Annex to Implementing Regulation (EU) No 1065/2012, entry 1k20716 on ‘*Lactobacillus plantarum* DSM 23375’ is deleted.

[4] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

Article 3
Transitional measures

The preparation specified in the Annex and feed containing it, which are produced and labelled before [***12 months*** *after the date of entry into force of the Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of the Regulation – Date to be inserted by the Service responsible for the publication*] 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,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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: technological additives. Functional group: silage additives								
1k20716	*Lactiplantibacillus plantarum* DSM 23375	**Additive composition** Preparation of *Lactiplantibacillus plantarum* DSM 23375 containing a minimum of 2×10^{10} CFU/g additive Solid form --- **Characterisation of the active substance** Viable cells of *Lactiplantibacillus plantarum* DSM 23375 --- **Analytical method**[1] Enumeration in the feed additive of *Lactiplantibacillus plantarum* DSM 23375: - Spread plate method using MRS Agar (EN 15787) Identification of *Lactiplantibacillus plantarum* DSM 23375: - Pulsed Field Gel Electrophoresis (PFGE) – CEN/TS 17697 or DNA sequencing	All animal species	-		-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum dose of the additive when used without combination with other micro-organisms as silage additives: $1x10^8$ CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[1] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category: technological additives. Functional group: silage additives								
		methods						

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Pediococcus pentosaceus* NCIMB 30168 as a feed additive for all animal species and amending Implementing Regulation (EU) No 1119/2012

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Pediococcus pentosaceus* NCIMB 30168 as a feed additive for all animal species and amending Implementing Regulation (EU) No 1119/2012

(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) The preparation of *Pediococcus pentosaceus* NCIMB 30168 was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 1119/2012[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Pediococcus pentosaceus* NCIMB 30168 as a feed additive for all animal species, requesting the additive to be classified in the additive category 'technological additives' and in the functional group 'silage additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 May 2023[3] that the preparation of *Pediococcus pentosaceus* NCIMB 30168 remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive should be considered a respiratory sensitiser but no conclusions could be drawn on the skin sensitisation and on the skin and eye irritancy potential of the additive. The Authority also indicated that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

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1 OJ L 268, 18.10.2003, p. 29.

2 Commission Implementing Regulation (EU) No 1119/2012 of 29 November 2012 concerning the authorisation of preparations of *Pediococcus acidilactici* CNCM MA 18/5M DSM 11673, *Pediococcus pentosaceus* DSM 23376, NCIMB 12455 and NCIMB 30168, *Lactobacillus plantarum* DSM 3676 and DSM 3677 and *Lactobacillus buchneri* DSM 13573 as feed additives for all animal species (OJ L 330, 30.11.2012, p. 14).

3 EFSA Journal 2023;21(6):8046.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparation of *Pediococcus pentosaceus* NCIMB 30168 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005[4], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that the preparation of *Pediococcus pentosaceus* NCIMB 30168 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) As a consequence of the renewal of the authorisation of the preparation of *Pediococcus pentosaceus* NCIMB 30168 as a feed additive, Implementing Regulation (EU) No 1119/2012 should be amended.

(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

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) No 1119/2012

In the Annex to Implementing Regulation (EU) No 1119/2012, entry 1k2107 on ‘*Pediococcus pentosaceus* NCIMB 30168’ is deleted.

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.

[4] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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: technological additives. Functional group: silage additives								
1k2107	*Pediococcus pentosaceus* NCIMB 30168	**Additive composition** Preparation of *Pediococcus pentosaceus* NCIMB 30168 containing a minimum of 5×10^{10} CFU/g additive Solid form --- **Characterisation of the active substance** Viable cells of *Pediococcus pentosaceus* NCIMB 30168 --- **Analytical method**[1] Enumeration in the feed additive of *Pediococcus pentosaceus* NCIMB 30168: - Spread plate method using MRS Agar (EN 15786) Identification of *Pediococcus pentosaceus* NCIMB 30168: - Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697 or DNA sequencing	All animal species	-		-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum dose of the additive when used without combination with other micro-organism as silage additive: $1x10^8$ CFU/kg fresh material. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[1] Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
					CFU/kg of fresh material			
Category: technological additives. Functional group: silage additives								
		methods						

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Brussels, XXX
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[…](2023) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, as a feed additive for all poultry species for fattening, all poultry species for laying and weaned piglets (holder of authorisation: DSM Nutritional Products) and amending Implementing Regulation (EU) No 403/2013

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, as a feed additive for all poultry species for fattening, all poultry species for laying and weaned piglets (holder of authorisation: DSM Nutritional Products) and amending Implementing Regulation (EU) No 403/2013

(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 an authorisation.

(2) A preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, was authorised for 10 years as a feed additive for poultry for fattening and for laying and for weaned piglets by Commission Implementing Regulation (EU) No 403/2013[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, as a feed additive. 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 11 May 2023[3] that the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, remains safe for poultry for fattening and for laying and for weaned piglets, the consumers and the environment under the conditions of use currently authorised. It also concluded that the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-

[1] OJ L 268, 18.10.2003, p. 29.

[2] Commission Implementing Regulation (EU) No 403/2013 of 2 May 2013 concerning the authorisation of a preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase produced by *Trichoderma reesei* (ATCC 74444) as a feed additive for poultry for fattening and for laying and for weaned piglets and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005 and (EC) No 1876/2006 (holder of authorisation DSM Nutritional Products) (OJ L 121, 3.5.2013, p. 26).

[3] EFSA Journal 2023;21(6):8043.

1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, should be considered a potential respiratory sensitiser. In absence of data the Authority could not conclude on the potential of that preparation to cause skin and eye irritation or dermal sensitisation. It also indicated that there is no need for assessing the efficacy of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, in the context of the renewal of the authorisation. The Authority did 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.

(5) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(6) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, as a feed additive, Implementing Regulation (EU) No 403/2013 should be amended.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of 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

Renewal of authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) No 403/2013

Implementing Regulation (EU) No 403/2013 is amended as follows:

1. Article 1 is deleted;

2. the Annex is deleted.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12%			
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a1602i	DSM Nutritional Products	Endo-1,4-beta-xylanase (EC 3.2.1.8) Endo-1,3(4)-beta-glucanase (EC 3.2.1.6) Endo-1,4-beta-glucanase (EC 3.2.1.4)	***Additive composition*** Preparation of endo-1,4-beta-xylanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-glucanase, produced by *Trichoderma reesei* ATCC 74444, having a minimum activity of: - Endo-1,4-beta-xylanase 2700 U ([1]) /ml or g additive - Endo-1,3(4)-beta-glucanase 700 U ([2]) /ml or g additive - Endo-1,4-beta-glucanase 800 U ([3]) /ml or g additive Liquid or solid form. ***Characterisation of the active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8), endo-1,4-beta-glucanase (EC 3.2.1.6) and endo-1,3(4)-	All poultry species for fattening other than turkeys for fattening	-	Endo-1,4-beta-xylanase: 135 U Endo-1,3(4)-beta-glucanase: 35 U Endo-1,4-beta-glucanase: 40 U	-	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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*
				All poultry species for laying		Endo-1,4-beta-xylanase: 216 U Endo-1,3(4)-beta-glucanase: 56 U Endo-1,4-beta-glucanase: 64 U			
				Turkeys for fattening		Endo-1,4-beta-xylanase: 270 U			

([1]) One endo-1,4-beta-xylanase unit (U) is the amount of enzyme which releases 1 micromole of reducing sugar (xylose equivalent) per minute from wheat arabinoxylan at 40 °C and pH 5.0.
([2]) One endo-1,3(4)-beta-glucanase unit (U) is the amount of enzyme which releases 1 micromole of reducing sugar (glucose equivalent) per minute from barley beta-glucan at 40 °C and pH 5.0.
([3]) One endo-1,4-beta-glucanase unit (U) is the amount of enzyme which releases 1 micromole of reducing sugar (glucose equivalent) per minute from carboxy-methyl-cellulose at 40 °C and pH 5.0.

			beta-glucanase (EC 3.2.1.4), produced by *Trichoderma reesei* ATCC 74444 ***Analytical method (4)*** - For the determination of endo-1,4-beta-xylanase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the wheat arabinoxylan substrate. - For the determination of endo-1,3(4)-beta-glucanase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the barley betaglucan substrate. - For the determination of endo-1,4-beta-glucanase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the carboxy-methyl-cellulose substrate. - For the determination of endo-1,4-beta-xylanase in premixtures and compound feed: colorimetric method based on the enzymatic reaction on the azo-xylan (birchwood) substrate. - For the determination of endo-1,3(4)-beta-glucanase in premixtures and compound feed: colorimetric method based on the enzymatic reaction on the azo-barley-	Piglets (weaned)		Endo-1,3(4)-beta-glucanase: 70 U Endo-1,4-beta-glucanase: 80 U			

(4) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

			glucan substrate. - For the determination of endo-1,4-beta-glucanase in premixtures and compound feed: colorimetric method based on the enzymatic reaction on the azo-carboxy-methyl-cellulose substrate.						

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Brussels, XXX
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(POOL/G5/2023/6396156/6396156-EN CIS.docx)
[…](2023) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, the authorisation of that preparation as a feed additive for turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets (holder of the authorisation: Huvepharma NV) and amending Implementing Regulation (EU) 2015/2305

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, the authorisation of that preparation as a feed additive for turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets (holder of the authorisation: Huvepharma NV) and amending Implementing Regulation (EU) 2015/2305

(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 an authorisation.

(2) A preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 (previously taxonomically identified as *Trichoderma citrinoviride* Bisset (IM SD142)) was authorised for a period of 10 years as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets by Commission Implementing Regulation (EU) 2015/2305[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 for chickens for fattening, minor poultry species for fattening and weaned piglets, requesting that additive to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’. In accordance with Article 7 of Regulation (EC) No 1831/2003, that application also concerned the authorisation of new uses of the same preparation as a feed additive for turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3)of that Regulation.

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1 OJ L 268, 18.10.2003, p. 29.

2 Commission Implementing Regulation (EU) 2015/2305 of 10 December 2015 concerning the authorisation of a preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma Citrinoviride* Bisset (IM SD142) as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, and amending Regulations (EC) No 2148/2004 and (EC) No 1520/2007 (holder of authorisation Huvepharma NV) (OJ L 326, 11.12.2015, p. 43).

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 21 March 2023[3], that the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 remains safe for chickens for fattening, minor poultry species for fattening and weaned piglets, as well as for the consumers and the environment under the conditions of use currently authorised, and indicated that this conclusion on safety also applies to turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets. The Authority further concluded that the preparation is not considered skin corrosive or eye irritant. It stated that the preparation should be considered a skin sensitiser and a respiratory sensitiser, while no conclusion could be drawn on the potential of the additive to be a skin irritant. The Authority indicated that there was no need for assessing the efficacy of the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 in the context of the renewal of the authorisation for chickens for fattening, minor poultry species for fattening and weaned piglets, and considered that the conclusions on efficacy reached in chickens for fattening and weaned piglets can be extended to turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of endo-1,4-beta-glucanase as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), points (a) and (c), of Commission Regulation (EC) No 378/2005[4], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that preparation should be renewed for chickens for fattening, minor poultry species for fattening and weaned piglets, and the use of that preparation should be authorised for turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 as a feed additive for chickens for fattening, minor poultry species for fattening and weaned piglets, Implementing Regulation (EU) 2015/2305 should be amended.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of endo-1,4-beta-glucanase produced by *Trichoderma citrinoviride* IMI 360748 for chickens for fattening, minor poultry species for fattening and weaned piglets, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

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[3] EFSA Journal 2023;21(4):7954.

[4] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, for chickens for fattening, minor poultry species for fattening and weaned piglets, is renewed subject to the conditions laid down in that Annex.

Article 2

Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised for turkeys for fattening, all poultry species reared for laying or breeding, ornamental birds and suckling piglets, subject to the conditions laid down in that Annex.

Article 3

Amendments to Implementing Regulation (EU) 2015/2305

Implementing Regulation (EU) 2015/2305 is amended as follows:

1. Article 1 is deleted;

2. the Annex is deleted.

Article 4

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

Entry into force

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

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

Done at Brussels,

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 (Units of activity/kg of complete feedingstuff with a moisture content of 12%)		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a1616	Huvepharma NV	Endo-1,4-beta-glucanase (EC 3.2.1.4)	***Additive composition*** Preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* IMI 360748 having a minimum activity of 2000 CU ([1])/g. Solid or liquid form. ***Characterisation of the active substance*** Endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma citrinoviride* IMI 360748. ***Analytical method ([2])*** For the determination of endo-1,4- beta-glucanase in feed additive, premixtures and compound feeds: colorimetric method based on the quantification of water soluble dyed fragments (azurine) produced by the action of endo-1,4-beta-glucanase on azurine-crosslinked cellulose.	All poultry species for fattening All poultry species reared for laying or breeding Ornamental birds	-	500 CU	-	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 its use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP: insert precise date]*
				Suckling piglets Weaned piglets	-	350 CU	-		

([1]) One CU is the amount of enzyme that liberates 0,128 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4.5 and 30°C.
([2]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en