REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/454

of 20 March 2019

concerning the authorisation of preparations of alpha-amylase from *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251, or *Aspergillus oryzae* ATCC SD-5374, as well as a preparation of endo-1,4-beta-glucanase from *Trichoderma reesei* ATCC PTA-10001 as silage additives for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10(7) of Regulation (EC) No 1831/2003 in conjunction with Article 10(1) to (4) thereof sets out specific provisions for the evaluation of products used in the Union as silage additives.

(2) In accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003, the preparations of alpha-amylase (EC 3.2.1.1) produced by the following strains of *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251 or by *Aspergillus oryzae* ATCC SD-5374 as well as a preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma reesei* ATCC PTA-10001 were entered in the Register of feed additives as existing products belonging to the functional group of silage additives, for all animal species.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of the three preparations of alpha-amylase (EC 3.2.1.1) and a preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) as feed additives for all animal species.

(4) The application concerns the authorisation of preparations of alpha-amylase (EC 3.2.1.1) produced by *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251 or by *Aspergillus oryzae* ATCC SD-5374 as well as the preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma reesei* ATCC PTA-10001 as feed additives for all animal species, to be classified in the additive category 'technological additives'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 March 2018 ([2]) that, under the proposed conditions of use, the preparations concerned do not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the preparations concerned have the potential to improve the production of silage from easy, moderate and difficult to ensile forage materials. 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.

(6) The assessment of the preparations of alpha-amylase (EC 3.2.1.1) produced by *Bacillus amyloliquefaciens* DSM 9553, *Bacillus amyloliquefaciens* NCIMB 30251 or by *Aspergillus oryzae* ATCC SD-5374 as well as the preparation of endo-1,4-beta-glucanase (EC 3.2.1.4) produced by *Trichoderma reesei* ATCC PTA-10001 show that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised as specified in the Annex to this Regulation.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2018; 16(4):5224.

(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 preparations specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 20 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

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
					Units of activity of additive/kg of fresh material			
Technological additives: silage additives								
1k101	Alpha-amylase (EC 3.2.1.1)	*Additive composition* Preparation of alpha-amylase produced by: *Bacillus amyloliquefaciens* DSM 9553, having a minimum activity of 129 800 DNS [1]/g additive Solid form *Characterisation of the active substance* Alpha-amylase produced by *Bacillus amyloliquefaciens* DSM 9553 *Analytical method* [2] For the determination of alpha-amylase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the starch at pH 4,5 and 37 °C	All animal species	—	—	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Minimum dose of alpha-amylase when used without combination with other enzymes or microorganisms as silage additives 40 DNS/kg of 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 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.	11 April 2029
1k102	Alpha-amylase (EC 3.2.1.1)	*Additive composition* Preparation of alpha-amylase produced by *Bacillus amyloliquefaciens* NCIMB 30251, having a minimum activity of 101 050 DNS/g additive Solid form	All animal species	—	—	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Minimum dose of alpha-amylase when used without combination with other enzymes or microorganisms as silage additives 10 DNS/kg of fresh material.	11 April 2029

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
					Units of activity of additive/kg of fresh material			
		Characterisation of the active substance Alpha-amylase produced by *Bacillus amyloliquefaciens* NCIMB 30251 *Analytical method* (2) For the determination of alpha-amylase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the starch at pH 4,5 and 37 °C					3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	
1k103	Alpha-amylase (EC 3.2.1.1)	*Additive composition* Preparation of alpha-amylase produced by *Aspergillus oryzae* ATCC SD-5374 having a minimum activity of 235 850 DNS/g additive Solid forms *Characterisation of the active substance* Alpha-amylase produced by *Aspergillus oryzae* ATTC SD-5374 *Analytical method* (2) For the determination of alpha-amylase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the starch at pH 4,5 and 37 °C	All animal species	—	—	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Minimum dose of alpha-amylase when used without combination with other enzymes or microorganisms as silage additives 23 DNS/kg of 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 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.	11 April 2029

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
					Units of activity of additive/kg of fresh material			
1k104	Endo-1,4-beta-glucanase (EC 3.2.1.4)	*Additive composition* Preparation of endo-1,4-beta-glucanase produced by *Trichoderma reesei* ATCC PTA-10001 having a minimum activity of 2 750 DNS ([3])/g additive Solid form *Characterisation of the active substance* Endo-1,4-beta-glucanase produced by *Trichoderma reesei* ATCC PTA-10001 *Analytical method* ([2]) For the determination of endo-1,4-beta-glucanase in the feed additive: colorimetric (DNS) method based on the enzymatic hydrolysis of the carboxymethyl cellulose (CMC) at pH 4,5 and 37 °C	All animal species	—	—	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Minimum dose of endo-1,4-beta-glucanase when used without combination with other enzymes or microorganisms as silage additives 7 DNS/kg of 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 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.	11 April 2029

([1]) 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as maltose equivalents in µmol per g per min at pH 4,5 and 37 °C from starch under specified conditions of the assay.
([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
([3]) 1 DNS (3,5-dinitrosalicylic acid) unit is the amount of reducing sugar released as glucose equivalents in µmol per g per min at pH 4,5 and 37 °C from carboxymethyl cellulose (CMC) under specified conditions of the assay.