Commission Implementing Regulation (EU) 2015/47 of 14 January 2015 concerning the authorisation of a preparation of alpha-amylase produced by Bacillus licheniformis (DSM 21564) as a feed additive for dairy cows (holder of the authorisation DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. Z.o.o) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/47

of 14 January 2015

concerning the authorisation of a preparation of alpha-amylase produced by *Bacillus licheniformis* (DSM 21564) as a feed additive for dairy cows (holder of the authorisation DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. Z.o.o)

(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 alpha-amylase produced by *Bacillus licheniformis* (DSM 21564). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of alpha-amylase produced by *Bacillus licheniformis* (DSM 21564) as a feed additive for dairy cows to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (the Authority) concluded in its opinions of 15 June 2012[(2)] and 9 October 2013[(3)] that, under the proposed conditions of use, the preparation of alpha-amylase produced by *Bacillus licheniformis* (DSM 21564) does not have an adverse effect on animal health, human health or the environment. Furthermore, the Authority noted that during the first half of the lactation period the additive significantly increased milk yield. It considered that this conclusion cannot, however, be drawn for the whole lactation period. 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 alpha-amylase produced by *Bacillus licheniformis* (DSM 21564) 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

Authorisation

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

Article 2

This Regulation shall enter into force on the 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, 14 January 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/47. (See end of Document for details)*

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.									
4a21	DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. Z.o.o	alpha-amylase EC 3.2.1.1	*Additive composition* Preparation of alpha-amylase produced by *Bacillus licheniformis* (DSM 21564) having a minimum activity of: solid form: 160 KNU[a]/g; liquid form: 240 KNU/g. *Characterisation of the active substance* alpha-amylase EC 3.2.1.1	Dairy cows	—	300 KNU	—	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting. 2. For use up to the 14th week of lactation. 3. For safety: breathing protection glasses and gloves shall be used during handling.	4 February 2025

a 1 KNU is the amount of enzyme which liberates 6 micromole p-nitrophenol per minute from 1,86 mM ethylidene-G7-p-nitrophenyl-maltoheptaoside at pH 7,0 and 37 °C.

b 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