Commission Implementing Regulation (EU) 2020/1796 of 30 November 2020 concerning the authorisation of L-glutamine produced by Corynebacterium glutamicum NITE BP-02524 as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1796

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concerning the authorisation of L-glutamine produced by *Corynebacterium glutamicum* NITE BP-02524 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of L-glutamine produced by *Corynebacterium glutamicum* NITE BP-02524 as a feed additive for all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of L-glutamine produced by *Corynebacterium glutamicum* NITE BP-02524 as a feed additive for all animal species to be classified in the additive category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’, and in the additive category ‘sensory additives’, functional group ‘flavouring compounds’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 18 March 2020[(2)] that, under the proposed conditions of use, L-glutamine produced by *Corynebacterium glutamicum* NITE BP-02524 does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the additive is an efficacious source of glutamine for all animal species and that for the supplemental L-glutamine to be fully efficacious in ruminants, it should be protected against degradation in the rumen.

(5) As regards the use as flavouring, the Authority states that no further demonstration of efficacy is necessary when used at the recommended dose. The use of L-glutamine as flavouring compound is not authorised in water for drinking. At the recommended dose,

L-glutamine as a flavouring compound is unlikely to pose any concern. The fact that the use of the L-glutamine is not authorised as flavouring in water for drinking does not preclude its use in compound feed which is administered via water. Restrictions and conditions should be provided for to allow a better control of L-glutamine as a flavouring compound. For L-glutamine, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures.

(6) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of L-glutamine produced by *Corynebacterium glutamicum* NITE BP-02524 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

(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

1 The substance specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’ is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

2 The substance specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’ is authorised as a feed 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, 30 November 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
						mg/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives. Functional group: amino acids, their salts and analogues									
3c451		L-glutamine	*Additive composition:* Powder with a minimum content of 98 % L-glutamine *Characterisation of the active substance:* L-glutamine produced by fermentation with *Corynebacterium glutamicum* NITE BP-02524 IUPAC name: (2S)-2,5-diamino-5-oxopentanoic acid CAS number: 56-85-9 Einecs number: 200-292-1 Chemical formula: $C_5H_{10}N_2O_3$	All animal species				1. L-glutamine may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall	21.12.2030

a 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

			Analytical method[a]: For the identification of L-glutamine in the feed additive: —	Food Chemical Codex ‘L-glutamine monograph’					be indicated.
			For the quantification of glutamine in the feed additive, premixtures, compound feed and feed materials: —	Ion exchange chromatography coupled to post-column derivatisation and optical detection) (IEC-VIS/ FLD).				3. ‘The supplementation with L-glutamine shall ensure an adequate amino acid profile in feed and address potential glutamine shortages during critical periods of life.’	Declaration to be made on the label of the additive and premixture:

Category: Sensory additives. Functional group: Flavouring compounds

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feed			

a 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

						with a moisture content of 12 %			
3c451		L-glutamine	*Additive composition:* Powder with a minimum content of 98 % L-glutamine *Characterisation of the active substance:* L-glutamine produced by fermentation with *Corynebacterium glutamicum* NITE BP-02524 IUPAC name: (2S)-2,5-diamino-5-oxopentanoic acid CAS number: 56-85-9 Einecs number: 200-292-1 Chemical formula: $C_5H_{10}N_2O_3$ Flavis number: 17.007 *Analytical method*[a]: For the identification of L-	All animal species				1. L-glutamine may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. In the directions for use of the additive and premixture, the storage conditions and the	21.12.2030

a 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

			glutamine in the feed additive: —	Food Chemical Codex 'L-glutamine monograph'					stability to heat treatment shall be indicated.
			For the quantification of glutamine in the feed additive and premixtures: —	Ion exchange chromatography coupled to visible or fluorescence detection with post-column derivatisation and optical detection) (IEC-VIS/FLD), as described in EN ISO 17180:2013				4.	On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg'.
								5.	The functional group, the identification number, the name and the added amount of the active substance

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									shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg.

a 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

(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) EFSA Journal 2020; 18(4):6075

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1796.