Commission Implementing Regulation (EU) 2018/129 of 25 January 2018 concerning the authorisation of L-arginine produced by Corynebacterium glutamicum KCCM 80099 as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/129

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concerning the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 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-arginine produced by *Corynebacterium glutamicum* KCCM 80099 as a feed additive for use in feed and in water for drinking. 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 L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 as a feed additive for all animal species to be classified in the additive category ‘nutritional additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 17 May 2017[(2)] that, under the proposed conditions of use, L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 does not have an adverse effect on animal health, consumer health or the environment and that no safety concerns for users would arise provided that appropriate protective measures are taken.

(5) The Authority also concluded that the additive is an effective source of the amino acid arginine for all animal species and that for the supplemental L-arginine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority expressed in its opinions a concern over the safety of L-arginine when administered via water for drinking. However, no maximum content for L-arginine is proposed by the Authority. Moreover, the Authority recommends supplementation with L-arginine in appropriate amounts. Thus, it is in the case of supplementation with L-

arginine, particularly via drinking water appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids.

(6) 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.

(7) The assessment of L-arginine produced by *Corynebacterium glutamicum* KCCM 80099 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 substance 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

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 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, 25 January 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/129. (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**
						mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c362	—	L-arginine	*Additive composition* Powder with a minimum content of L-arginine of 98 % (on a dry matter basis) and a maximum content of 0,5 % water *Characterisation of the active substance* L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced by fermentation with *Corynebacterium glutamicum* KCCM 80099.	All animal species				1. L-arginine may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment	15 February 2028

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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/129. (See end of Document for details)*

			Chemical formula: $C_6H_{14}N_4O_2$ CAS number: 74-79-3 *Analytical method*[a] For the characterisation of L-arginine in the feed additive: — Food Chemical Codex ‘L-arginine monograph’. For the quantification of arginine in the feed additive and water: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS). For the quantification of arginine in premixtures, feed materials and				and the stability in water for drinking shall be indicated.	
							4. Declarations to be made on the labelling of the additive and premixtures: ‘The supplementation with L-arginine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.’	
							5. For users of the additive and premixtures, feed business operators	

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