Commission Implementing Regulation (EU) 2020/1033 of 15 July 2020 concerning the renewal of the authorisation of L-arginine produced by Corynebacterium glutamicum ATCC 13870 and the authorisation of L-arginine produced by Corynebacterium glutamicum KCCM 80182 as feed additives for all animal species, and repealing Regulation (EC) No 1139/2007 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1033

of 15 July 2020

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(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) L-arginine produced by *Corynebacterium glutamicum* ATCC 13870 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EC) No 1139/2007[(2)].

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of L-arginine produced by *Corynebacterium glutamicum* ATCC 13870 as feed additive for all animal species, requesting this additive to be classified in the additive category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’. This application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003 and included a request to change the strain designation to *Corynebacterium glutamicum* NITE SD 00285.

(4) 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 80182 as a feed additive for use in feed and in water for drinking for all animal species. The application concerns the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 80182 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 additive category 'sensory additives', functional group 'flavouring compounds'. This 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 opinions of 3 April 2019[3] and 14 May 2019[4] that, under the proposed conditions of use, L-arginine produced by *Corynebacterium glutamicum* NITE SD 00285 and by *Corynebacterium glutamicum* KCCM 80182 does not have an adverse effect on animal health, consumer health or the environment. It also stated for L-arginine produced by *Corynebacterium glutamicum* NITE SD 00285 to be irritant to skin, corrosive to eyes and hazardous upon inhalation. For L-arginine produced by *Corynebacterium glutamicum* KCCM 80182, it stated to be corrosive to skin and eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. 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.

(6) The Authority expressed in its opinion on L-arginine produced by *Corynebacterium glutamicum* KCCM 80182 a concern on the safety of the simultaneous oral administration of the amino acid via water for drinking and feed. However, the Authority did not propose a maximum content for L-arginine. Moreover, the Authority recommends supplementation with L-arginine in appropriate amounts. Thus, in the case of supplementation with L-arginine via water for drinking it is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids.

(7) Restrictions and conditions should be provided for to allow for a better control for L-arginine when used as flavouring. For L-arginine used as flavouring recommended content should be indicated on the label. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(8) As regards the use of L-arginine as a flavouring, the Authority states that no further demonstration of efficacy is necessary when the substance is used at the recommended dose level. The use of L-arginine as a flavouring compound is not authorised in water for drinking. At the recommended dose, L-arginine as flavouring compound is not likely to pose any concern for the dietary supply with all the essential and conditionally essential amino acids.

(9) 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.

(10) The assessment of L-arginine produced by *Corynebacterium glutamicum* NITE SD 00285 and by *Corynebacterium glutamicum* KCCM 80182 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.

(11) As a consequence of the renewal of the authorisation of L-arginine produced by *Corynebacterium glutamicum* ATCC 13870 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 1139/2007 should be repealed.

(12) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for L-arginine produced by *Corynebacterium glutamicum* ATCC 13870, it is appropriate to provide a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(13) The fact that the use of the L-arginine is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.

(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

1 The authorisation of L-arginine produced by *Corynebacterium glutamicum* ATCC 13870, belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’, is renewed subject to the conditions laid down in the Annex.

2 L-arginine produced by *Corynebacterium glutamicum* KCCM 80182, belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’, and in the additive category ‘sensory additives’, functional group ‘flavouring compounds’ is authorised as an additive in animal nutrition subject to the conditions laid down in the Annex.

Article 2

1 L-arginine produced by *Corynebacterium glutamicum* ATCC 13870 and premixtures containing it, which are produced and labelled before 5 February 2021 in accordance with the rules applicable before 5 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substances referred to in point 1, which are produced and labelled before 5 August 2021 in accordance with the rules applicable before 5 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3 Feed materials and compound feed containing the substances referred to in point 1, which are produced and labelled before 5 August 2022 in accordance with the rules applicable before 5 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Regulation (EC) No 1139/2007 is repealed.

Article 4

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, 15 July 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 of nutritional additives. Functional group: amino acids, their salts and analogues									
3c364		L-arginine	**Additive composition:** Powder with a minimum content of L-arginine of 98 % (on a dry matter basis) and a maximum content of 15 % water **Characterisation of the active substance:** L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced by fermentation with *Corynebacterium glutamicum* NITE	All animal species				1. L-Arginine 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	5 August 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

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

c 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