COMMISSION IMPLEMENTING REGULATION (EU) 2019/12

of 3 January 2019

concerning the authorisation of L-arginine 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 two applications were submitted for the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 10741P and by *Escherichia coli* NITE BP-02186 as a feed additive for use in feed and in water for drinking for all animal species. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The applications concern the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 10741P as a feed additive for all animal species to be classified in the additive category 'nutritional additives' and of L-arginine produced by *Escherichia coli* NITE BP-02186 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 opinions of 18 April 2018 ([2]) and 19 April 2018 ([3]) that, under the proposed conditions of use, L-arginine produced by *Escherichia coli* NITE BP-02186 and by *Corynebacterium glutamicum* KCCM 10741P 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 potential nutritional imbalances of when L-arginine is administered as amino acid 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, in the case of supplementation with L-arginine as amino acid via drinking water it is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids.

(6) 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-arginine as flavouring compound is not authorised in water for drinking. At the recommended dose, L-arginine as flavouring compound is unlikely to pose any concern for the dietary supply with all the essential and conditionally essential amino acids.

(7) 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.

(8) The assessment of L-arginine 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.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2018;16(5):5276
([3]) EFSA Journal 2018;16(5):5277

(10) 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

1. The substances L-arginine produced by *Corynebacterium glutamicum* KCCM 10741P and L-arginine produced by *Escherichia coli* NITE BP-02186 specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues' are authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

2. The substance L-arginine produced by *Escherichia coli* NITE BP-02186 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

Entry into force

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, 3 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

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.									
3c363	—	L-arginine	*Additive composition* Powder with a minimum content of L-arginine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water *Characterisation of the active substance* L-arginine ((S)-2-amino-5-guanidino-pentanoic acid) produced by fermentation with *Escherichia coli* NITE BP-02186. Chemical formula: $C_6H_{14}N_4O_2$ CAS number: 74-79-3 *Analytical method* (1) For the identification 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)	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, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. The moisture content shall be indicated on the label of the additive. 5. Declaration to be made on the label of the additive and premixture: '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.'	24 January 2029

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 %			
			For the quantification of arginine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009					6. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment, including breathing protection.	
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-guanidino-pentanoic acid) produced by fermentation with *Corynebacterium glutamicum* KCCM10741P Chemical formula: $C_6H_{14}N_4O_2$ CAS number: 74-79-3 *Analytical method* (1) For the identification of L-arginine in the feed additive: — Food Chemical Codex 'L-arginine monograph'	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, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. Declaration to be made on the label of the additive and premixture: '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.'	24 January 2029

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 %			
			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, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009					5. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment, including breathing protection.	
Category: Sensory additives. Functional group: Flavouring compounds									
3c363	—	L-Arginine	*Additive composition* Powder with a minimum content of L-arginine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water *Characterisation of the active substance* L-arginine ((S)-2-amino-5-guanidino-pentanoic acid) produced by fermentation with — *Escherichia* coli NITE BP-02186 Chemical formula: $C_6H_{14}N_4O_2$ CAS number 74-79-3 FLAVIS No 17.003	All animal species	—	—	—	1. L-arginine 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 stability to heat treatment shall be indicated. 4. The moisture content shall be indicated on the label of the additive.	24 January 2029

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 %			
			Method of analysis (1) For the identification of L-arginine in the feed additive: — Food Chemical Codex 'L-arginine monograph' For the quantification of arginine in the feed additive — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) For the quantification of arginine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009					5. On the label of the additive and premixture the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.' 6. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment, including breathing protection.	

(1) 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