COMMISSION IMPLEMENTING REGULATION (EU) 2023/649

of 20 March 2023

concerning the authorisation of L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 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* CGMCC 20516. 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-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 June 2022 ([2]) that, under the proposed conditions of use, L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 does not have an adverse effect on consumer safety or the environment, or on animal health when supplemented in appropriate amounts to the diet according to the nutritional needs of the target species and when nutritional imbalances caused by the simultaneous administration of L-arginine via water for drinking and feed are prevented.

(5) The Authority further concluded that exposure of users by inhalation is possible. The applicant provided the safety data sheet required in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]) which demonstrates that the additive may cause eyes and skin irritation.

(6) The Authority concluded that the additive has the potential to be efficacious for all animal species. 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* CGMCC 20516 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. 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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2022;20(7):7427.
([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(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, 20 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 additive/kg of complete feed with a moisture content of 12 %			
3c365	L-arginine	*Additive composition* ≥ 98,5 % L-arginine (on a dry matter basis) and ≤ 1 % of water Solid form *Characterisation of the active substance* L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced by *Corynebacterium glutamicum* CGMCC 20516 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 determination of arginine in the feed additive and water: — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS). For the determination of arginine in premixtures and complete feed: — Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F).	All species	—	—	—	1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixture shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 3. The label of the additive and premixture shall indicate the following: '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.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing, skin and eye protection.	11.4.2033

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.