



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/7829679/2022 CIS
(POOL/G5/2022/7829679/7829679-EN
CIS.docx)
[...](2022) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of L-arginine produced by *Corynebacterium glutamicum*
CGMCC 20516 for all animal species.**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

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concerning the authorisation of L-arginine produced by *Corynebacterium glutamicum* CGMCC 20516 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 nutrition¹, 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. The 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* 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 2022² 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 for users by inhalation is possible. The applicant provided the data sheets required in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council³ which demonstrate that the additive may cause eye and skin irritation.

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).

- (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 that additive.
- (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 additive 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,

For the Commission
The President
Ursula VON DER LEYEN