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COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of L-tyrosine as a feed additive for all animal species and repealing Implementing Regulation (EU) No 101/2014

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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concerning the renewal of the authorisation of L-tyrosine as a feed additive for all animal species and repealing Implementing Regulation (EU) No 101/2014

(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-tyrosine was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 101/2014[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of L-tyrosine as a feed additive for all animal species, requesting that additive to be classified in the category 'nutritional additives' and in the functional group 'amino acids, their salts and analogues'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 June 2024[3] that the use of the feed additive in animal nutrition remains safe for the target species, consumers, and the environment. As regards the safety for the user, the Authority considered that l-tyrosine was not an irritant to skin or eyes, but it could not conclude on the potential of l-tyrosine to be a dermal sensitiser. Exposure to the additive by inhalation of persons handling it is likely. The Authority considered that there is no need to assess the efficacy of L-tyrosine, as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation. The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of L-tyrosine as a feed additive in the context of the previous authorisation are still valid and applicable

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1 OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

2 Commission Implementing Regulation (EU) No 101/2014 of 4 February 2014 concerning the authorisation of L-tyrosine as a feed additive for all animal species (OJ L 34, 05/02/2014, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2014/101/oj).

3 EFSA Journal, 22(7), e8845.

for the current application. In accordance with Article 5(4), point (c) of Commission Regulation (EC) No 378/2005[4], an evaluation report of the Reference Laboratory is therefore not required.

(5) In view of the above, the Commission considers that L-tyrosine satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(6) As a consequence of the renewal of the authorisation of L-tyrosine as a feed additive, Implementing Regulation (EU) No 101/2014 should be repealed.

(7) 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
Renewal of the authorisation

The authorisation of 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 renewed subject to the conditions laid down in that Annex.

Article 2
Repeal of Implementing Regulation (EU) No 101/2014

Implementing Regulation (EU) No 101/2014 is repealed.

Article 3
Transitional measures

1. The feed additive L-tyrosine, as authorised by Implementing Regulation No 101/2014 and premixtures containing that additive, which are produced and labelled before [*6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*], may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before [*12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the*

[4] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

publication], may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are produced and labelled before [*24 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*], may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

Article 4

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,

For the Commission
The President
Ursula VON DER LEYEN