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

of **XXX**

**concerning the authorisation of L-tryptophan produced by *Escherichia coli* KCCM
80210 as a feed additive for all animal species**

(Text with EEA relevance)

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

of **XXX**

concerning the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 80210 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 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-tryptophan produced by *Escherichia coli* KCCM 80210. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The application concerns the authorisation of L-tryptophan produced by *Escherichia coli* KCCM 80210 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’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 27 January 2021² that, under the proposed conditions of use, L-tryptophan produced by *Escherichia coli* KCCM 80210 does not have an adverse effect on the health of non-ruminant animals, consumer safety or the environment. To be safe for ruminants, the L-tryptophan should be protected against degradation in the rumen. The Authority stated that the additive under assessment is considered a mild eye irritant. The endotoxin activity of the additive and its dusting potential indicate a risk by inhalation. 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.
- (5) The Authority considered L-tryptophan produced by *Escherichia coli* KCCM 80210 an efficacious source of the essential amino acid tryptophan for non-ruminant animals; for the supplemental L-tryptophan produced by *Escherichia coli* KCCM 80210 to be as efficacious in ruminants as in non-ruminants, it should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the

¹ OJ L 268, 18.10.2003, p. 29.

² EFSA Journal 2021;19(3):6425.

method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) The assessment of L-tryptophan produced by *Escherichia coli* KCCM 80210 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 as specified in the Annex to this Regulation.
- (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

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,

For the Commission
The President
Ursula VON DER LEYEN