



Brussels, **XXX**
SANTE/12754/2019
[...](2020) **XXX** draft

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

of **XXX**

concerning the authorisation of zinc chelate of lysine and glutamic acid as a feed additive for all animal species

(Text with EEA relevance)

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

of **XXX**

concerning the authorisation of zinc chelate of lysine and glutamic acid 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 zinc chelate of lysine and glutamic acid. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of zinc chelate of lysine and glutamic acid as a feed additive for all animal species to be classified in the additive category ‘nutritional additives’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 2 July 2019² that, under the proposed conditions of use, zinc chelate of lysine and glutamic acid does not have an adverse effect on animal health and consumer health. It also concluded that the additive is considered as a potential skin and respiratory sensitizer and stated a risk for the users of the additive upon inhalation. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that that additive does not pose an additional risk for the environment compared to other compounds of zinc and that it is an efficacious source of zinc 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.
- (5) The assessment of that additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are, subject to the relevant protective measures for the users of the additive, satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.

¹ OJ L 268, 18.10.2003, p. 29.

² EFSA Journal 2019;17(7):5782.

- (6) 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 ‘compounds of trace elements’, 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