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

of **XXX**

concerning the authorisation of Iron(III) citrate chelate as a feed additive for piglets and minor porcine species (holder of the authorisation: Akeso Biomedical, Inc. USA, represented in the Union by Pen & Tec Consulting SLU)

(Text with EEA relevance)

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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 ferric citrate chelate. 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 ferric citrate chelate as a feed additive for piglets and minor porcine species (suckling and weaned) to be classified in the additive category 'zootechnical additives' and functional group 'other zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 November 2019² and 27 January 2021³ that, under the proposed conditions of use, ferric citrate chelate does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that the additive should be considered a skin sensitiser and a potential eye irritant. 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. 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 ferric citrate chelate 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.

¹ OJ L 268, 18.10.2003, p. 29.

² EFSA Journal 2019;17(11):5916.

³ EFSA Journal 2021;19(3):6455.

- (6) In order to align the name of this substance with other, already authorised iron containing additives, 'ferric' should be replaced with the synonym term 'iron(III)'.
- (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 'zootechnical additives' and to the functional group 'other zootechnical additives', 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