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EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of ferric tyrosine chelate as a feed additive for all poultry species for fattening, all poultry species reared for laying, and turkeys and minor poultry species reared for breeding (holder of 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 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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of ferric tyrosine 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 tyrosine chelate as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening, minor poultry species to point of lay, turkeys for fattening and rearing to point of lay, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional groups ‘gut flora stabilisers’ and ‘other zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 23 January 2019[2] and 14 March 2024[3] that, under the proposed conditions of use, ferric tyrosine chelate is safe for the target species, the consumers and the environment. It also concluded that the additive poses a risk to users by inhalation, and should also be considered as an irritant to skin, eyes and mucous membranes. Due to the presence of nickel, ferric tyrosine chelate should also be considered as a dermal and respiratory sensitiser. The Authority further concluded that, under the proposed conditions of use, ferric tyrosine chelate has the potential to improve zootechnical parameters of birds and to reduce the caecal load of *Campylobacter* spp. by at least 1 log10-units in the target species, thus with a potential impact to reduce the risk of human campylobacteriosis. The Authority recommended including a specification for maximum lithium content in a potential authorisation of the additive, while it did not

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
[2] EFSA Journal 2019;17(2):5608.
[3] EFSA Journal 2024;22:e8734.

consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed and water submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) On 24 July 2024, the applicant informed the Commission that the maximum nickel content in the additive is now set at 20 mg nickel/kg of feed additive instead of 50 mg/kg, and the maximum lithium content in the additive is now set at 50 mg lithium/kg of feed additive instead of 1200 mg/kg. In addition, on 10 July 2024, the applicant withdrew the application as regards the authorisation of ferric tyrosine chelate in the functional group 'gut flora stabilisers'.

(6) In view of the above, the Commission considers that ferric tyrosine chelate satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of ferric tyrosine chelate should be authorised. 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.

(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
Authorisation

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
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