



2024/3162

19.12.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/3162

of 18 December 2024

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)

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 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 1 200 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'.

⁽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.

- (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, 18 December 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: other zootechnical additives (reduction of the caecal load of <i>Campylobacter</i> spp.)									
4d28	Akeso Biomedical, Inc. USA, represented in the Union by Pen & Tec Consulting SLU	Ferric tyrosine chelate	<p>Additive composition Ferric tyrosine chelate having a minimum content of 820 g/kg total tyrosine, 80 g/kg iron and 60 g/kg total nitrogen. 50–100 g/kg of a graphite coloured microtracer. Impurities: — Nickel ≤ 20 mg/kg — Lithium ≤ 50 mg/kg Solid form.</p> <p>Characterisation of the active substance Ferric tyrosine chelate: — C₂₇H₃₀FeN₃O₉ — CAS number: 202406-43-7 Produced by chemical synthesis.</p> <p>Analytical method ⁽¹⁾ For the quantification of total iron in the feed additive: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510); or</p>	All poultry species for fattening All poultry species reared for laying Turkeys and minor poultry species reared for breeding	–	20	200	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	8 January 2035

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: other zootechnical additives (reduction of the caecal load of <i>Campylobacter</i> spp.)									
			<div>— inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621) with pressure digestion; or</div> <div>— atomic absorption spectrometry, AAS (EN ISO 6869).</div> <div>For the determination of tyrosine in the feed additive: ion exchange chromatography method with post-column derivatisation and photometric detection (Commission Regulation (EC) No 152/2009).</div> <div>For the determination of the added content of ferric tyrosine chelate in premixtures and compound feed: enumeration of colour coated particles of the graphite coloured microtracer present at fixed mass ratio in the feed additive.</div>						

(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.