COMMISSION IMPLEMENTING REGULATION (EU) 2021/1412

of 27 August 2021

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)

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 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 2019 ([2]) and 27 January 2021 ([3]) 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 respiratory and 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 concluded that the feed additive has the potential to improve zootechnical parameters of weaned piglets and that this conclusion can be extended to sucking piglets for the period in which solid feed is given and extrapolated to all minor porcine 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 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.

(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,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019;17(11):5916.
([3]) EFSA Journal 2021;19(3):6455.

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the 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 additive/kg of complete feed with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters).									
4d22	Akeso Biomedical, Inc. USA, represented in the Union by Pen & Tec Consulting SLU	Iron(III) citrate chelate	**Additive composition:** Iron(III) citrate chelate as a powder with a minimum iron(III) content of 15 %, a maximum iron content of 20 %, a maximum nickel content of 50 ppm 5-10 % of a coloured microtracer and a maximum of 10 % moisture. **Characterisation of the active substance:** 2-hydroxy-1,2,3-propanetricarboxylic acid iron(III) Chemical formula: $C_6H_5FeO_7$ CAS number: 3522-50-7. **Analytical method** (1) For the quantification of total iron in the feed additive: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510); or	Piglets and minor porcine species (suckling and weaned)	-	550	825	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin, eyes and breathing protection. 3. Declaration to be made on the label of the additive and premixture: — content of iron — content of microtracer	19.9.2031

			— inductively coupled plasma-atomic emission spectrometry, ICP-AES with pressure digestion (EN 15621); — atomic absorption spectrometry, AAS (EN ISO 6869); For the quantification of citrate in the feed additive: — ion-exchange high performance liquid chromatography (HPLC) coupled to ultraviolet (UV) detection; For the determination of the added content of iron(III) citrate chelate in premixtures, compound feed and feed materials: — enumeration of colour coated particles of the microtracer present at fixed mass ratio in the feed additive.					4. The amount of iron contained in the additive shall be taken into consideration for the calculation of the total iron content in complete feed.	

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports