COMMISSION IMPLEMENTING REGULATION (EU) 2022/1457

of 2 September 2022

amending Implementing Regulation (EU) 2017/2330 as regards the terms of authorisation of iron (II) chelate of amino acids hydrate 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 nutrition ([1]), and in particular Article 13(3) 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 an authorisation.

(2) The use of iron (II) chelate of amino acids hydrate as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) 2017/2330 ([2]).

(3) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of iron (II) chelate of amino acids hydrate as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, if modified as proposed by the applicant. That modification consists in the extension of the protein sources for the amino acids and in the introduction of a minimum specification for free amino acids and of a tighter specification of the iron content. The request was accompanied by the relevant supporting data.

(4) The Authority concluded in its opinion of 29 September 2021 ([3]) that the modifications of the terms of authorisation applied for do not modify the conclusions reached in the previous assessments on the safety for the target species, consumers, environment and efficacy of the feed additive. The Authority concluded that the additive should be considered a skin and eye irritant and a skin sensitizer, and stated a potential risk due to exposure by inhalation. 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 the proposed modifications to the authorisation shows that the conditions for authorisation as provided for in Article 5 of Regulation (EC) No 1831/2003 are satisfied.

(6) For reasons of clarity, the composition of the additive should be modified to include the indication that the additive consists of a preparation.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) 2017/2330 of 14 December 2017 concerning the authorisation of Iron(II) carbonate, Iron(III) chloride hexahydrate, Iron(II) sulphate monohydrate, Iron(II) sulphate heptahydrate, Iron(II) fumarate, Iron(II) chelate of amino acids hydrate, Iron(II) chelate of protein hydrolysates and Iron(II) chelate of glycine hydrate as feed additives for all animal species and of Iron dextran as feed additive for piglets and amending Regulations (EC) No 1334/2003 and (EC) No 479/2006 (OJ L 333, 15.12.2017, p. 41).

([3]) EFSA Journal 2021;19(10):6894.

(7) Implementing Regulation (EU) 2017/2330 should therefore be amended accordingly.

(8) 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

In the Annex to Implementing Regulation (EU) 2017/2330, the entry for iron (II) chelate of amino acids hydrate is amended in accordance with the Annex to this Regulation.

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, 2 September 2022.

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
						Content of element (Fe) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
‘3b106	-	Iron (II) chelate of amino acids hydrate	*Additive composition:* Preparation of Iron(II) amino acid complex where the iron and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 9 % iron. *Characterisation of the active substance:* Chemical formula: $Fe(x)_{1-3}{\cdot}nH2O$, x = anion of any amino acid from soya protein hydrolysate. Maximum 10 % of molecules exceeding 1500 Da. *Analytical methods* (1): For the quantification of amino acid content in the feed additive: — ion exchange chromatography with post-column derivatisation and optical detection (IEC-VIS/FLD) — For the quantification of the free amino acid content in the feed additive: — ion exchange chromatography with post-column derivatisation and optical detection (IEC-VIS/FLD),	All animal species	-	-	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to 1 week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	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 appropriate organisational measures to address the potential risks by inhalation, dermal or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing, skin and eye protection.	4 January 2028

			For the quantification of total iron in the feed additive: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869) For the quantification of total iron in premixtures: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869) or — inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053) For the quantification of total iron in feed materials and compound feed: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or — inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053)						
3b106i	-	Iron (II) chelate of amino acids hydrate	*Additive composition:* Preparation of iron (II) amino acid complex, where the iron and the amino acids are chelated via coordinate covalent bonds, as a powder with an iron content of 9 – 10 % and a minimum of 18 % free amino acids.	All animal species	-	-	Ovine: 500 (total [2]) Bovines and poultry: 450 (total [2])	1. The additive shall be incorporated into feed in the form of a premixture.	4 January 2028

			Characterisation of the active substance: Chemical formula: $Fe(x)_{1-3} \bullet nH_2O$, where x is equal to any amino acid coming from hydrolysed protein sources from feathers or plants; Maximum 10 % of molecules exceeding 1500 Da. *Analytical methods* ([1]): For the quantification of the free amino acid content in the feed additive: — ion exchange chromatography with post-column derivatisation and optical detection (IEC-VIS/FLD), Commission Regulation (EC) No 152/2009 (Annex III,F) and EN ISO 17180 For the quantification of total iron in the feed additive: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869) For the quantification of total iron in premixtures: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (ISO 6869) or — inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053)				Piglets up to 1 week before weaning: 250 (total ([2])) Pet animals: 600 (total ([2])) Other species: 750 (total ([2]))	2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal or eyes contact in particular due to the content of heavy metals.. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing, skin and eye protection. 3. For additives produced from hydrolysis of animal protein, the animal origin (*avian species*) shall be indicated on the label of the additive and premixtures.	

			For the quantification of total iron in feed materials and compound feed: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510 or EN 15621) or — atomic absorption spectrometry, AAS (Commission Regulation (EC) No 152/2009 (Annex IV-C) or ISO 6869) or — inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053)						

(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
(2) The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed (iron/kg complete feed)'