Commission Implementing Regulation (EU) 2020/1795 of 30 November 2020 concerning the authorisation of iron chelate of lysine and glutamic acid as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1795

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concerning the authorisation of iron chelate of lysine and glutamic acid 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 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 iron chelate of lysine and glutamic acid. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of iron chelate of lysine and glutamic acid as a feed additive for all animal species to be classified in the additive category ‘nutritional additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 4 July 2019[(2)] and 25 May 2020[(3)] that, under the proposed conditions of use, iron chelate of lysine and glutamic acid does not have an adverse effect on animal health and consumer safety. It also concluded that the additive is an eye irritant, skin and respiratory sensitizer, and stated a risk for the users of the additive upon 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 also concluded that that the additive does not pose an additional risk for the environment compared to other authorised compounds of iron and that it is an efficacious source of iron for all animal 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 the additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are, subject to the relevant protective measures for the users of the additive, satisfied. Accordingly, the use of the additive should be authorised.

(6) 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 ‘nutritional additives’ and to the functional group ‘compounds of trace elements’, 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, 30 November 2020.

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									
3b111		Iron chelate of lysine and glutamic acid	*Additive composition* Mixture of chelates of iron with lysine and chelates of iron with glutamic acid in a ratio of 1:1 as a powder with an iron content between 15 and 16 %, a lysine content between 19 and 21 %,	All animal species			Ovine: 500 (total[b]) Bovines and poultry: 450 (total[b]) Piglets up to one week before weaning: 250 mg/day (total[b]) Pet animals: 600 (total[b]) Other species: 750 (total[b])	1. The additive shall be incorporated into feed in the form of a premixture. 2. Iron chelate of lysine and glutamic acid may be placed on the market and used as an additive consisting of a preparation.	2.2.2030

a 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

b The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

				a glutamic acid content between 18,5 and 21,5 % and a maximum of 3 % moisture				3.	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
				Characterisation of the active substances Chemical formulas: Iron-2,6-diaminohexanoic acid, chloride and hydrogen sulfate salt: $C_6H_{17}ClFeN_2O_7S$ Iron-2-aminopentanedioic acid, sodium and hydrogen sulfate salt: $C_5H_{12}FeNNaO_{10}S$					
				Analytical methods[a] For the quantification of the lysine and glutamic					

a 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

b The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

			acid content in the feed additive: —	ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) For proving the chelated structure of the feed additive: — mid-infrared (IR) spectrometry together with the determination of the content of the trace element and lysine and glutamic acid in the					used with appropriate personal protective equipment, including breathing protection.

a 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

b The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

				feed additive						
			For the quantification of total iron in the feed additive: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621).						
			For the quantification of total iron in premixtures:							

a 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

b The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

			— Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621); or — Inductively Coupled Plasma – Mass Spectrometry, ICP-MS (EN 17053). For the quantification of total iron in					

a 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

b The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

			feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009, Annex IV-C) or — Atomic Absorption Spectrometry, AAS (EN ISO 6869) or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510) or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-						

a 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

b The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

			—	AES (EN 15621) or Inductively Coupled Plasma – Mass Spectrometry, ICP-MS (EN 17053).					

a 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

b The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

(**1**) OJ L 268, 18.10.2003, p. 29.

(**2**) *EFSA Journal* 2019;17(7):5792.

(**3**) *EFSA Journal* 18(6):6164.

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1795.