



2024/1055

11.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1055

of 10 April 2024

concerning the authorisation of iron(II) – betaine complex 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(II) – betaine complex. 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 iron(II) – betaine complex as a feed additive for all animal species, requesting that additive to be classified in the category ‘nutritional additives’ and in the functional group ‘compounds of trace elements’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 5 September 2023 ⁽²⁾ that, under the proposed conditions of use, iron(II) – betaine complex is safe for, consumers and the environment provided that the maximum authorised levels for total iron in feed are not exceeded. The Authority further concluded that iron(II)-betaine complex is safe for chickens for fattening. This conclusion can be extrapolated to all animal species and categories provided that the maximum authorised levels in the EU for total iron in feed are not exceeded. The Authority concluded that iron(II) – betaine complex, owing to the presence of nickel, is considered a skin and respiratory sensitiser. It is an eye irritant, but it is non-irritant to the skin. The Authority concluded that the substance is efficacious as a source of iron in all animal species and categories. The Authority did 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) In view of the above, the Commission considers that iron(II)– betaine complex satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. The Commission further concludes that for safety reasons the additive should be incorporated in feed via premixtures. 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.
- (6) 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, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal 2023;21(9):8250.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

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, 10 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	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 the element (Fe) in mg/kg of complete feed with a moisture content of 12 % or in mg element (Fe)/day			

Category: nutritional additives. Functional group: compounds of trace elements

3b112	Iron(II) – betaine complex	<i>Additive composition</i> Iron betaine complex with a minimum of 14 % of iron and a minimum of 36 % of betaine. Nickel: maximum 58 mg/kg. Solid form. <i>Characterisation of the active substances</i> Name: catena-[diaqua sulfato-μ2-(trimethylammonio)acetato-iron(II)] Chemical formula: [Fe (H₂O)₂((CH₃)₃NCH₂COO)(SO₄)_n] <i>Specifications</i> Minimum of 14 % of iron, Minimum 36 % betaine, Sulphur: 9 %–12 %. Maximum 5 % moisture. <i>Analytical methods ⁽¹⁾</i> For the quantification of total iron in the feed additive: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or — Atomic absorption spectrometry, AAS (ISO 6869).	Ovines	—	—	500 mg/kg	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 the 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 breathing, eye and skin protective equipment.	1 May 2034
			Bovines	—	—	450 mg/kg		
			Piglets	Until one week before weaning	—	250 mg/day		
			Poultry	—	—	450 mg/kg		
			Pets	—	—	600 mg/kg		
			Other animal species	—	—	750 mg/kg		

		For the quantification of total iron in pre-mixtures: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) or — Atomic absorption spectrometry, AAS (ISO 6869) or — Inductively coupled plasma-mass spectrometry, ICP-MS (EN 17053). For the quantification of total iron in compound feed: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621 or EN 15510) 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). For the quantification of betaine in the feed additive: — High performance liquid chromatography with refraction index detection (HPLC-RI).						
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		For the quantification of sulphur and sulphate in the feed additive: — Inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15621). Proof of complex formation between iron, betaine and sulphate ⁽²⁾: Powder X-ray diffraction (XRD).						
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⁽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⁾ Stoe Stadi P diffractometer in Guinier geometry using Cu-Kα1 radiation (Johann Gemonochromator) and a Stoe imageplate detector IP-PSD.