

COMMISSION REGULATION (EU) No 350/2010**of 23 April 2010****concerning the authorisation of manganese chelate of hydroxy analogue of methionine 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 the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.
- (4) From the opinion of the European Food Safety Authority ('the Authority') adopted on 9 December 2009 ⁽²⁾, read in combination with the opinions of 15 September 2009 ⁽³⁾ and 15 April 2008 ⁽⁴⁾, it results that manganese chelate of hydroxy analogue of methionine does not have an adverse effect on animal health, human health or the environment. According to the opinion of 15 April 2008, the use of that preparation

may be considered as a source of available manganese and fulfils the criteria of a nutritional additive for all animal species. The Authority recommends appropriate measures for user safety. It 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of that preparation 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 preparation should be authorised, as specified in the Annex to this Regulation.
- (6) By Commission Regulation (EU) No 103/2010 of 5 February 2010 concerning the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for chickens for fattening ⁽⁵⁾ that preparation was already authorised as a feed additive for chickens for fattening. That Regulation should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation 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

Regulation (EU) No 103/2010 is repealed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ The EFSA Journal (2010) 8(1): 1424.

⁽³⁾ The EFSA Journal (2009) 7(9): 1316.

⁽⁴⁾ The EFSA Journal (2008) 692, 1.

⁽⁵⁾ OJ L 35, 6.2.2010, p. 1.

Article 3

This Regulation shall enter into force on the 20th day following 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, 23 April 2010.

For the Commission
The President
José Manuel BARROSO

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 (Mn) in mg/kg of complete feedingstuff with a moisture content of 12 % | | | |
| Category of nutritional additives. Functional group: compounds of trace elements | | | | | | | | | |
| 3b5.10 | — | Manganese chelate of hydroxy analogue of methionine | <p>Characterisation of the additive:</p> <p>Manganese chelate of hydroxy analogue of methionine containing 15,5 %-17 % manganese and 77 %-78 % (2-hydroxy-4-methylthio) butanoic acid</p> <p>Mineral oil: ≤ 1 %</p> <p>Analytical method ⁽¹⁾:</p> <p>Inductively coupled plasma atomic emission spectrometry (ICP-AES) according to EN 15510:2007</p> | All species | — | — | Fish: 100 (total) Other species: 150 (total) | <p>1. The additive has to be incorporated into feed in the form of a premixture.</p> <p>2. For user safety: breathing protection, safety glasses and gloves should be worn during handling.</p> | 14 May 2020 |

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: <http://irmm.jrc.ec.europa.eu/crl-feed-additives>