Commission Implementing Regulation (EU) 2017/1490 of 21 August 2017 concerning the authorisation of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1490

of 21 August 2017

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(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The manganese compounds manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate were authorised without a time limit by Commission Regulations (EC) No 1334/2003[(3)] and (EC) No 479/2006[(4)] in accordance with Directive 70/524/EEC. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the re-evaluation of manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as feed additives for all animal species. Additionally, in accordance with Article 7 of that Regulation, an application was submitted for manganese hydroxychloride as feed additive for all animal species. The applicants requested that those additives be classified in the additive category ‘nutritional additives’. The applications were

accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 23 October 2014[(5)], 23 October 2014[(6)], 19 March 2015[(7)], 18 February 2016[(8)] and 13 May 2016[(9)] that, under the proposed conditions of use, manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide do not have an adverse effect on animal health, consumer safety and the environment. Due to scientific considerations, the Authority recommended to rename manganous oxide as manganese (II) oxide and manganese hydroxychloride as dimanganese chloride trihydroxide, in order to avoid potential misunderstandings. The Authority also recommended splitting manganese chelate of amino acids into the following two groups, in view of its chemical characteristics: manganese chelate of amino acids hydrate and manganese chelate of protein hydrolysates.

(5) The Authority noted that handling manganese (II) oxide is hazardous by inhalation to the user. In the absence of adequate data, the additive should be considered as a potential skin and eye irritant and as a dermal sensitiser. The Authority also noted that handling manganous sulphate monohydrate poses a risk to users upon inhalation exposure and is an eye irritant. It was also observed that handling manganese chelate of amino acids hydrate poses a possible hazard to the respiratory tract and the health of users. In the absence of adequate data regarding irritancy to the skin and eyes and dermal sensitisation, this latter additive should also be considered as a potential skin and eye irritant and as a skin and respiratory sensitiser. With respect to manganese chelate of glycine hydrate, the Authority noted that this additive may irritate skin and eyes. Finally, in the absence of specific data, the Authority could not conclude on the safety for the user when handling dimanganese chloride trihydroxide. Consequently, appropriate protective measures should be taken with respect to the additives concerned, in order to avoid that safety concerns for the users would arise.

(6) The Authority further concluded that manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide are effective sources of manganese. 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied, except for water for drinking. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation and their use via water for drinking should be denied.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1490. (See end of Document for details)*

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as authorised by Regulation (EC) No 1334/2003, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(9) 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

Authorisation

The substances specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’, are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Denial

Authorisation of the substances specified in the Annex as additives belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’ is denied for use in water for drinking.

Article 3

Transitional measures

1 The substances manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as authorised by Regulations (EC) No 1334/2003 and (EC) No 479/2006, and premixtures containing those substances, which are produced and labelled before 11 March 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 11 September 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3 Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 11 September 2019 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1490. (See end of Document for details)*

Article 4

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, 21 August 2017.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/1490. (See end of Document for details)*

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 feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b501	—	Manganous chloride tetrahydrate	*Additive composition* Manganous chloride tetrahydrate, as a powder, with a minimum content of 27 % manganese. *Characterisation of the active substance* Manganous chloride tetrahydrate Chemical formula: $MnCl_2 \cdot 4H_2O$ CAS Number: 13446-34-9 *Analytical methods*[a] For the identification reactions of chloride in the feed additive:	All animal species	—	—	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Manganous chloride tetrahydrate may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators	11 September 2027

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 Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for official control of feed (OJ L 54, 26.2.2009, p. 1).