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 (Text with EEA relevance)

[[X1]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

(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 iron compounds Ferric chloride hexahydrate, Ferric oxide, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate were authorised without a time limit by Commission Regulation (EC) No 1334/2003[(3)] and Commission Regulation (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 Ferric chloride hexahydrate, Ferric oxide, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate as feed additives for all animal species.

Additionally, in accordance with Article 7 of that Regulation, an application was submitted for Iron dextran as feed additive for piglets. 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) Due to scientific considerations, the European Food Safety Authority ('the Authority') recommended in its opinions of 19 June 2013[(5)], 30 January 2014[(6)], 5 March 2014[(7)], 28 April 2014[(8)] and 27 January 2016[(9)] to rename Ferric as Iron(III) and Ferrous as Iron(II), in order to avoid potential misunderstandings. The Authority also recommended splitting Iron(II) chelate of amino acids into the following two groups, in view of its chemical characteristics: Iron(II) chelate of amino acids hydrate and Iron(II) chelate of protein hydrolysates.

(5) The Authority concluded that, under the proposed conditions of use, 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 do not have anadverse effect on animal health, consumer safety and the environment. Considering the capacities to be respiratory, eye and skin irritants due to the presence of Nickel in each iron (II) and iron (III) compound, appropriate protective measures should be taken with respect to the handling of the additives concerned and premixtures containing them, in order to avoid that safety concerns for the users would arise.

(6) In its opinions of 24 January 2017[(10)], the Authority concluded that, under the proposed conditions of use, Iron dextran does not have an adverse effect on animal health, consumer safety and the environment, and that no safety concerns for users would arise provided that appropriate protective measures are taken.

(7) The Authority further concluded that 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, Iron(II) chelate of glycine hydrate and Iron dextran are effective sources of iron; however, the bioavailability of Iron(II) carbonate varies significantly and is considered to be lower than that for Iron(II) sulphate. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(8) The assessment 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 for piglets 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 prohibited.

(9) As a result of the granting new authorisations for 'Ferric chloride hexahydrate', 'Ferrous carbonate', 'Ferrous chelate of amino acids hydrate', 'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferrous sulphate monohydrate' and 'Ferrous chelate of glycine, hydrate' by this Regulation and of the denial of the authorisation for 'Ferric oxide', the entries of these substances in Regulations (EC) No 479/2006 and (EC) No 1334/2003 should be deleted.

(10) As the Authority could not conclude in its opinions of 24 May 2016[(11)] on the safety of ferric oxide for the target species, the additive and feed containing it should be withdrawn from the market as soon as possible. For practical reasons, however, a limited transitional period should be allowed for the withdrawal from the market of the products concerned in order to enable operators to comply properly with the withdrawal obligation.

(11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for Ferric chloride hexahydrate, Ferrous carbonate, Ferrous chelate of amino acids hydrate, Ferrous chelate of glycine hydrate, Ferrous fumarate, Ferrous sulphate heptahydrate and Ferrous sulphate monohydrate as authorised by Regulation (EC) No 1334/2003 and Regulation (EC) No 479/2006, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(12) 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:

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 333 of 15 December 2017).

[X1 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.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 333 of 15 December 2017).

Article 2

Special conditions of use

The authorised substances specified in the Annex as additives belonging to the additive category ‘nutritional additives’ and to the functional group ‘compounds of trace elements’ shall not be used in water for drinking.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 333 of 15 December 2017).

Article 3

Denial

The authorisation for ferric oxide is hereby denied and the substance shall no longer be used as nutritional feed additive.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 333 of 15 December 2017).

Article 4

Amendment to Regulation (EC) No 1334/2003

In the Annex to Regulation (EC) No 1334/2003, from the entry E1 on the element Iron-Fe the following additives, their chemical formulas and descriptions are deleted: ‘Ferric chloride hexahydrate’, ‘Ferrous carbonate’, ‘Ferrous chelate of amino acids hydrate’,

'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferrous sulphate monohydrate' and 'Ferric oxide'.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 333 of 15 December 2017).

Article 5

Amendment to Regulation (EC) No 479/2006

In the Annex to Regulation (EC) No 479/2006, the entry E1 on the additive 'Ferrous chelate of glycine, hydrate' is deleted.

Editorial Information

X1 Substituted by Corrigendum to 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 (Official Journal of the European Union L 333 of 15 December 2017).

Article 6

Transitional measures

1 The substances 'Ferric chloride hexahydrate', 'Ferrous carbonate', 'Ferrous chelate of amino acids hydrate', 'Ferrous chelate of glycine hydrate', 'Ferrous fumarate', 'Ferrous sulphate heptahydrate', 'Ferric oxide' and 'Ferrous sulphate monohydrate' as authorised by Commission Regulation (EC) No 1334/2003 and Commission Regulation (EC) No 479/2006, and premixtures containing those substances, which are produced and labelled before 4 July 2018 in accordance with the rules applicable before 4 January 2018 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 4 January 2019 in accordance with the rules applicable before 4 January 2018 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 4 January 2020 in accordance with the rules applicable before 4 January 2018 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.