CORRIGENDA

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)

On page 41, the text of Commission Implementing Regulation (EU) 2017/2330 should read as follows:

'**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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).
([3]) Commission Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements (OJ L 187, 26.7.2003, p. 11).
([4]) Commission Regulation (EC) No 479/2006 of 23 March 2006 as regards the authorisation of certain additives belonging to the group compounds of trace elements (OJ L 86, 24.3.2006, p. 4).

(4) Due to scientific considerations, the European Food Safety Authority ('the Authority') recommended in its opinions of 19 June 2013 ([1]), 30 January 2014 ([2]), 5 March 2014 ([3]), 28 April 2014 ([4]) and 27 January 2016 ([5]) 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 an adverse 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 ([6]), 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 ([7]) 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,

([1]) EFSA Journal 2013;11(7):3287.
([2]) EFSA Journal 2014;12(2):3566.
([3]) EFSA Journal 2014;12(3):3607.
([4]) EFSA Journal 2015;13(5):4109.
([5]) EFSA Journal 2016;14(2):4396.
([6]) EFSA Journal 2017;15(2):4701.
([7]) EFSA Journal 2016;14(6):4508.

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

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.

Article 3

Denial

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

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'.

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.

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.

Article 7

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, 14 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

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 % or in mg element (Fe)/day or week			
Category of nutritional additives. Functional group: compounds of trace elements									
3b101		Iron(II) carbonate (siderite)	*Additive composition:* Powder sourced from mined ore, containing siderite, with a minimum content of 70 % $FeCO_3$ and of 39 % total iron *Characterisation of the active substance:* Chemical formula: $FeCO_3$ CAS Number: 563–71–3 *Analytical methods* (1): For the identification of iron and carbonate in the feed additive: — European Pharmacopoeia Monograph 2.3.1. For the crystallographic characterisation of the feed additive: — X-Ray diffraction. For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species except piglets, calves, chicken up to 14 days and turkey up to 28 days	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) carbonate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 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 contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

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 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in 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-AES (CEN/TS 15621).					4. In the labelling of the additive and premixtures containing it, the following shall be indicated: "Iron(II) carbonate should not be used as iron source for young animals due to its limited bioavailability."	

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 % or in mg element (Fe)/day or week			
3b102	—	Iron(III) chloride hexahydrate	*Additive composition:* Iron(III) chloride hexahydrate, as a powder with a minimum content of 19 % iron. *Characterisation of the active substance:* Chemical formula: $FeCl_3 \cdot 6H_2O$ CAS Number: 10025–77–1 *Analytical methods* (1): For the identification of iron and chloride in the feed additive: — European Pharmacopoeia Monograph 2.3.1. For the crystallographic characterisation of the feed additive: — X-Ray diffraction. For the quantification of the ferric chloride hexahydrate in the feed additive: — titration with sodium thiosulfate (Ph. Eur Monograph 1515). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(III) chloride hexahydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a liquid premixture. 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 contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

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 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in 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-AES (CEN/TS 15621).						

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 % or in mg element (Fe)/day or week			
3b103	—	Iron(II) sulphate monohydrate	*Additive composition:* Iron(II) sulphate monohydrate, as powder or granules with a minimum content of 29 % iron. *Characterisation of the active substance:* Chemical formula: $FeSO_4 \cdot H_2O$ CAS Number: 17375–41–6 *Analytical methods* (1): For the identification of iron and sulphate in the feed additive: — European Pharmacopoeia Monograph 2.3.1. For the crystallographic characterisation of the feed additive: — X-Ray diffraction. For the quantification of the iron(II) sulphate monohydrate in the feed additive: — titration with ammonium and cerium nitrate (Ph. Eur Monograph 0083); or — titration with potassium dichromate (EN 889). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) sulphate monohydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 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 contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

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 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in 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-AES (CEN/TS 15621).						

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 % or in mg element (Fe)/day or week			
3b104	—	Iron(II) sulphate heptahydrate	*Additive composition:* Iron(II) sulphate heptahydrate, as a powder with a minimum content of 18 % iron. *Characterisation of the active substance:* Chemical formula: $FeSO_4 \cdot 7H_2O$ CAS Number: 7782–63–0 *Analytical methods* (1): For the identification of iron and sulphate in the feed additive: — European Pharmacopoeia Monograph 2.3.1. For the crystallographic characterisation of the feed additive: X-Ray diffraction. For the quantification of the iron(II) sulphate heptahydrate in the feed additive: — titration with ammonium and cerium nitrate (Ph. Eur Monograph 0083); or — titration with potassium dichromate (EN 889). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) sulphate heptahydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 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 contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

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 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in 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-AES (CEN/TS 15621).						

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 % or in mg element (Fe)/day or week			
3b105		Iron(II) fumarate	*Additive composition:* Iron(II) fumarate, as a powder with a minimum content of 30 % iron. *Characterisation of the active substance:* Chemical formula: $C_4H_2FeO_4$ CAS Number: 141–01–5 *Analytical methods* (1): For the quantification of the Iron(II) fumarate in the feed additive: — titration with cerium sulphate (Ph. Eur Monograph 0902). For the quantification of total iron in the feed additive and premixtures: — 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 (CEN/TS 15621).	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) fumarate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 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 contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	

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 % or in mg element (Fe)/day or week			
			For the quantification of total iron in 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-AES (CEN/TS 15621).						
3b106	—	Iron(II) chelate of amino acids hydrate	*Additive composition:* Iron(II) amino acid complex where the iron and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 9 % iron.	All animal species	—	—	Ovine: 500 (total [2]) Bovines and poultry: 450 (total [2]) Piglets up to one week before weaning: 250 mg/day (total [2])	1. Iron(II) chelate of amino acids may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture.	4 January 2028

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 % or in mg element (Fe)/day or week			
			Characterisation of the active substance: Chemical formula: $Fe(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid from soya protein hydrolysate. Maximum of 10 % of the molecules exceeding 1 500 Da. *Analytical methods* (1): For the quantification of amino acid content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Commission Regulation (EC) No 152/2009, Annex III, F). For the quantification of total iron in the feed additive and premixtures: — 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 (CEN/TS 15621).				Pet animals: 600 (total (2)) Other species: 750 (total (2))	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 contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	

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 % or in mg element (Fe)/day or week			
			For the quantification of total iron in 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-AES (CEN/TS 15621).						
3b107	—	Iron(II) chelate of protein hydrolysates	*Additive composition:* Iron(II) chelate of protein hydrolysates as a powder with a minimum content of 10 % iron. Minimum of 50 % iron chelated.	All animal species	—	—	Ovine: 500 (total [2]) Bovines and poultry: 450 (total [2]) Piglets up to one week before weaning: 250 mg/day (total [2])	1. Iron(II) chelate of protein hydrolysates may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture.	4 January 2028

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 % or in mg element (Fe)/day or week			
			Characterisation of the active substance: Chemical formula: $Fe(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid from soya protein hydrolysate. *Analytical methods* (1): For the quantification of protein hydrolysates content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Commission Regulation (EC) No 152/2009, Annex III, F). For the qualitative verification of the chelation of the iron in the feed additive: — Fourier Transformed Infrared (FTIR) spectroscopy followed by multivariate regression methods (to be updated by EURL) (3). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or				Pet animals: 600 (total (2)) Other species: 750 (total (2))	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 contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	

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 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in 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-AES (CEN/TS 15621).						

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 % or in mg element (Fe)/day or week			
3b108	—	Iron(II) chelate of glycine hydrate	*Additive composition:* Iron(II) chelate of glycine, hydrate, as a powder with a minimum content of 15 % iron. Moisture: maximum 10 %. *Characterisation of the active substance:* Chemical formula: $Fe(x)_{1-3} \cdot nH_2O$, x = anion of glycine. *Analytical methods* (1): For the quantification of the glycine content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Commission Regulation (EC) No 152/2009, Annex III, F). For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Ovine: 500 (total (2)) Bovines and poultry: 450 (total (2)) Piglets up to one week before weaning: 250 mg/day (total (2)) Pet animals: 600 (total (2)) Other species: 750 (total (2))	1. Iron(II) chelate of glycine hydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into feed in the form of a premixture. 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 contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	4 January 2028

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 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in 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-AES (CEN/TS 15621).						

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 % or in mg element (Fe)/day or week			
3b110		Iron dextran 10 %	*Additive composition:* Colloidal, aqueous solution of iron dextran with 25 % iron dextran (10 % total iron, 15 % dextran), 1,5 % sodium chloride, 0,4 % phenol and 73,1 % water *Characterisation of the active substance:* Iron dextran Chemical formula: $(C_6H_{10}O_5)n \cdot [Fe(OH)_3]m$ IUPAC name: ferric hydroxide dextran (α,3-α1,6 glucan) complex CAS Number: 9004-66-4 *Analytical methods* (1): For the characterisation of the feed additive: — British and US Pharmacopeia Iron Dextran monographs. For the quantification of total iron in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	Suckling piglets	—	—	200 mg/day once in the first week of life and 300 mg/day once in the second week of life	1. For users of the additive, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive shall be used with appropriate personal protective equipment. 2. Indicate in the instructions of use: — "The additive shall be fed only individually directly via a complementary feed." — "The additive shall not be administered to piglets deficient in vitamin E and/or selenium." — "The simultaneous use of other iron compounds shall be avoided during the administration period (first 2 weeks of life) of iron dextran 10 %."	4 January 2028

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 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621). For the quantification of total iron in 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						

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 % or in mg element (Fe)/day or week			
			— Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621).						

(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) The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.
(3) The method might be supplemented with another method. In this case, the Reference Laboratory will update its evaluation report and publish the applicable method on: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports'