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►B ►C1 **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) ◄

(OJ L 333, 15.12.2017, p. 41)

Corrected by:

►C1 Corrigendum, OJ L 351, 30.12.2017, p. 202 (2017/2330)

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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)

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.

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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.

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ANNEX

Identification number of the additive	Name of the holder ofauthorisation	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

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Identification number of the additive	Name of the holder ofauthorisation	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.’	

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Identification number of the additive	Name of the holder ofauthorisation	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

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Identification number of the additive	Name of the holder ofauthorisation	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).						

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Identification number of the additive	Name of the holder ofauthorisation	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:	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

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Identification number of the additive	Name of the holder ofauthorisation	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			
			— 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). 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).						

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Identification number of the additive	Name of the holder ofauthorisation	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:	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

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Identification number of the additive	Name of the holder ofauthorisation	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			
			— 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). 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).						

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Identification number of the additive	Name of the holder ofauthorisation	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.	

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Identification number of the additive	Name of the holder ofauthorisation	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. *Characterisation of the active substance:* Chemical formula: $Fe(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid from soya protein hydrolysate.	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

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Identification number of the additive	Name of the holder ofauthorisation	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			
			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.	

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Identification number of the additive	Name of the holder ofauthorisation	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

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Identification number of the additive	Name of the holder ofauthorisation	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:				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.	

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Identification number of the additive	Name of the holder ofauthorisation	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			
			— 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). 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).						

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Identification number of the additive	Name of the holder ofauthorisation	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

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Identification number of the additive	Name of the holder ofauthorisation	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).						

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Identification number of the additive	Name of the holder ofauthorisation	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.'	4 January 2028

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Identification number of the additive	Name of the holder ofauthorisation	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).					— ‘The simultaneous use of other iron compounds shall be avoided during the administration period (first 2 weeks of life) of iron dextran 10 %.’	

([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