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)

# [<sup>X1</sup>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<sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- 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<sup>(2)</sup>.
- (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<sup>(3)</sup> and Commission Regulation (EC) No 479/2006<sup>(4)</sup> 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<sup>(5)</sup>, 30 January 2014<sup>(6)</sup>, 5 March 2014<sup>(7)</sup>, 28 April 2014<sup>(8)</sup> and 27 January 2016<sup>(9)</sup> 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<sup>(10)</sup>, 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<sup>(11)</sup> 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).

# [<sup>X1</sup>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.

#### **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 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*.

#### **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).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

#### ANNEX

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**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are ci	irrently no known outstanding effects for the
Commission Implementing Regulation (E	U) 2017/2330. (See end of Document for details)

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**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

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**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

			Plasma - Atomic Emission Spectron ICP- AES (EN 15510) or Inductive Coupled Plasma - Atomic Emission Spectron after pressure digestion ICP- AES (CEN/ TS 15621).	netry, ely n netry			
3b102	chloride	Additive compositi raten(III) chloride hexahydi as a powder with a minimum content of 19 % iron. Characte of the active substanc Chemica formula: FeCl <sub>3</sub> 6H <sub>2</sub> O CAS Number:	<i>tian</i> imal species rate, n erisation e: 1		Ovine: 500 (total <sup>b</sup> ) Bovines and poultry: 450 (total <sup>b</sup> ) Piglets up to one week before weaning 250 mg/ day (total <sup>b</sup> ) Pet animals: 600 (total <sup>b</sup> )	1. 2.	4 January shoarde hexahydrate may be placed on the market and used as an additive consisting of a preparation. The additive shall

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

10025- 77-1     Other species: 77-1     be incorporated incorporated incorporated into feed additive:       For the identification of iron and chloride in the feed additive:     Curopean Pharmacopoeia Monograph 2.3.1.     Other species: 70     be incorporated into feed additive:       —     European Pharmacopoeia Monograph 2.3.1.     3.     For users of the feed additive:       —     European Pharmacopoeia Monograph 2.3.1.     3.     For users of the additive additive:       —     X- Ray diffraction.     3.     For users of the feed business operators shall establish operational procedures and appropriate organisational the by inhalation, dermal contact     additive additive additive and appropriate organisational risks cannot be reduced to							
77-1       species:       incorporated <i>methods</i> *:       (total*)       feed         For the       (total*)       feed         of iron       and       form         and       chloride       in         inthe       feed       in         feed       in       the         additive:       European       pharmacopocia         Monograph       2.3.1.       3.         For the       characterisation       of         feed       additive       additive         additive:        Ray         diffraction.       For the       operational         feed       additive       additive         additive:        X-         Ray       diffraction.       operational         of the       feed       address         feed       additive       appropriate         ord the       inthe       inhalation,         feed       address       the         additive:        K-         methodification       of       or         of the       feed       address       the         feed	1	0025-			Other		be
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For the identification of iron and chloride in the feed additive:in the form of a liquid premixture		-					
identification       identification         of iron       and         chloride       in the         feed       additive:         —       European         Pharmacopoeia       S.         Monograph       2.3.1.         For the       additive:         -       Pharmacopoeia         Monograph       2.3.1.         For the       and         characterisation       of the         feed       additive:         -       X-         Ray       diffraction.         For the       operators         quantification       of the         feed       address         additive:       -         -       X-         Ray       operational         of the       ferric         quantification       of the         feed       address         in the       feed         additive:       address         m       thissulfate         (Ph.       eyes         contact       or         with       sodium         thissulfate       or         (Ph.       eyes <td></td> <td></td> <td>•</td> <td></td> <td>(iotai )</td> <td></td> <td></td>			•		(iotai )		
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**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are currently no known outstanding effects for the	
Commission Implementing Regulation (EU) 2017/2330. (See end of Document for detail	ls)

iron in feed materials and compound		For the quantifica of total iron in feed materials and	Atomic Absorpti Spectron AAS (EN ISO 6866 or Inductive Coupled Plasma - Atomic Emissior Spectron ICP- AES (EN 15510); or Inductive Coupled Plasma - Atomic Emissior Spectron after pressure digestior ICP- AES (CEN/ TS 15621). ttion	netry, 9); ely n netry, ely				an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.
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Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/	 Dataila ai		at the follow	ving address	of the Pofora	nca Laborato	ny: https://ca	

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

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			Spectron			
			after	iou y		
			pressure			
			digestion	l,		
			ICP-			
			AES			
			(CEN/			
			TS			
			15621).			
			10021).			
D . 11	0.1 1	 			 ¥ 1 .	 ,

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are currently no known outstanding effects for the	ie
Commission Implementing Regulation (EU) 2017/2330. (See end of Document for a	etails)

3b103	 Iron(II)	Additive	All			Ovine:		4
00100		composi				500	1.	4 January
		dfatær(II)	species			(total <sup>b</sup> )		supphate
	monony	sulphate				Bovines		monohydrate
		monohy	Iroto			and		may
			maie,					be
		as				poultry:		placed
		powder				450		on
		or				(total <sup>b</sup> )		the
		granules				Piglets		market
		with a				up to		and
		minimur	n			one		used
		content				week		as
		of 29 %				before		
		iron.				weaning		an additive
		Characte	erisation			250 mg/		
		of the				day		consisting
		active				(total <sup>b</sup> )		of
		substanc	e:			Pet		a
		Chemica	1			animals:		preparation.
		formula:				600	2.	The
		FeSO <sub>4</sub>					۷.	additive
		· H <sub>2</sub> O				(total <sup>b</sup> )		shall
		CAS				Other		
		Number:				species:		be
		17375–				750		incorporated
		41–6				(total <sup>b</sup> )		into
			1					feed
		Analytic						in
		methods	:					the
		For the						form
		identifica	ation					of
		of iron						a
		and						premixture.
		sulphate					2	Г
		in the					3.	For
		feed						users
		additive:						of
		<u> </u>	Europea	n				the
			Pharmac	opoeia				additive
			Monogr					and
			2.3.1.	1				premixtures,
		For the						feed
		crystallo	graphic					business
		character	risation					operators
		of the	15411011					sĥall
		feed						establish
		additive:						operational
		auuitive.						procedures
								Procedures

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

For the quantific of the iron(II) sulphate	X- Ray diffraction. ation	and appropriate organisational measures to address the potential
monohyd in the feed additive:	titration	risks by inhalation, dermal contact
	with ammonium and cerium	or eyes contact. Where
	nitrate (Ph. Eur Monograph 0083);	risks cannot be reduced to
	or titration with potassium dichromate	an acceptable level by these
For the quantific	(EN 889).	procedures and measures, the
of total iron in the feed		additive and premixtures shall
additive and premixtu	res: Atomic	be used with appropriate
	Absorption Spectrometry, AAS (EN	personal protective equipment.
	ISO 6869); or Inductively Coupled	

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

	Plasma			
	-			
	Atomic			
	Emission	1		
	Spectron	netry.		
	ICP-			
	AES			
	(EN			
	15510);			
	or			
	Inductive	alv		
	Coupled	Jy		
	Plasma			
	riasilia			
	-			
	Atomic			
	Emission			
	Spectron	netry		
	after			
	pressure			
	digestion	l,		
	ICP-			
	AES			
	(CEN/			
	TS			
	15621).			
For the				
quantific	ation			
of total				
iron in				
feed				
materials	5			
and				
compour	nd			
feed:				
	Atomic			
	Absorpti	on		
	Spectron			
	AAS			
	(Commis	sion		
	Regulati	51011 51		
	(EC)			
	No			
		<b>)</b>		
	152/2009	,		
	Annex I	v -		
	C);			
	or			

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

		_	Atomic Absorpti Spectror AAS (EN ISO 686 or Inductiv Coupled	netry, 9); ely				
			Plasma - Atomic Emission Spectror ICP- AES (EN 15510) or Inductiv Coupled Plasma - Atomic Emission Spectror after pressure digestion ICP- AES	n netry, ely n netry				
			AES (CEN/ TS 15621).					
3b104	heptahyc	sulphate heptahyc as a powder with a minimum content of 18 % iron.	All <i>tiann</i> imal species Irate,		of the Refere	Ovine: 500 (total <sup>b</sup> ) Bovines and poultry: 450 (total <sup>b</sup> ) Piglets up to one week before	1.	4 fantiary subhate heptahydrate may be placed on the market and used as

The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed. b

<b>Changes to legislation:</b> There are currently no known outstanding effects for the	
Commission Implementing Regulation (EU) 2017/2330. (See end of Document for details	s)

Characterisationweaninganof the250 mg/additiv	e
of the 250 mg/ additive	e
<i>active</i> day consist	ing
substance: (total <sup>b</sup> ) of	-
Chemical Pet a	
formula: FeSO <sub>4</sub> animals: prepara	ation.
$\begin{array}{c} \cdot 7H_2O \\ CAS \end{array}$	
CAS (total <sup>*</sup> ) additiv	A
Number: Other shall	C
7782– species: be	
63-0 750	aratad
Analytical (total <sup>b</sup> ) incorpo	Jialeu
methods <sup>4</sup> :	
For the	
identification	
afiran	
IOIII III	
sulphate	
in the a	
feed	ture.
additive: 3. For	
— European users	
Pharmacopoeia of	
Monograph the	
2.3.1.	'A
For the and	C
crystallographic	tures
characterisation	luics,
of the busine	20
additive:	515
X-Ray establi	ah
	ures
	minto
in the second seco	
iron(II) organis	sational
sulphate measure	res
heptahydrate to	
in the addres	S
feed the	1
additive: potenti	al
— titration risks	
with by	
ammonium inhalat	
and dermal	
cerium	

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

	nitrate	contact
	(Ph.	or
	Eur	eyes
	Monograph	contact.
	0083);	Where
	or	risks
	titration	cannot
	with	be
	potassium	reduced
	dichromate	to
	(EN	an
	889).	acceptable
For the		level
quantific	ation	by
of total		these
iron		procedures
in the		and
feed		measures,
additive		the
and		additive
premixtu	ragi	and
premixu	Atomic	
		premixtures
	Absorption	be
	Spectrometry, AAS	used
		with
	(EN   EO (260))	
	ISO 6869);	appropriate
	Or Inductively	personal
	Inductively	protective
	Coupled Plasma	equipment.
	Plasilla	
	- Atomio	
	Atomic	
	Emission	
	Spectrometry,	
	ICP-	
	AES	
	(EN	
	15510);	
	or In the stimula	
	Inductively	
	Coupled	
	Plasma	
	-	
	Atomic	
	Emission	
	Spectrometry	

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

	after
	pressure
	digestion,
	ICP-
	AES
	(CEN/
	TS
E - n 4h -	15621).
For the	
quantifi	cation
of total	
iron in	
feed	
material	\$
and	
compou	nd
feed:	
	Atomic
	Absorption
	Spectrometry,
	AAS
	(Commission
	Regulation
	(EC)
	No
	152/2009,
	Annex IV-
	C);
	or
	Atomic
	Absorption
	Spectrometry,
	AAS
	(EN
	ISO 6869);
	Or Inductively
	Inductively
	Coupled
	Plasma
	Atomic
	Emission
	Spectrometry,
	ICP-
	AES
	(EN
Detaile af the analytical mothed are and ital	la at the following address of the Deference Laboratory, https://ae.aurone.au/

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

			15510) or Inductive Coupled Plasma – Atomic Emission Spectron after pressure digestion ICP- AES (CEN/ TS 15621).	n netry		
3b105	Iron(II) fumarate	Additive composit Iron(II) fumarate as a powder with a minimum content of 30 % iron. <i>Characte</i> of the active substanc Chemica formula: C <sub>4</sub> H <sub>2</sub> FeO CAS Number: 141– 01–5 <i>Analytica</i> methods <sup>a</sup> For the quantific of the Iron(II) fumarate in the	<i>tian</i> imal species , n <i>erisation</i> <i>e:</i> 1 D <sub>4</sub> <i>al</i> : ation		Ovine: 500 (total <sup>b</sup> ) Bovines and poultry: 450 (total <sup>b</sup> ) Piglets up to one week before weaning 250 mg/ day (total <sup>b</sup> ) Pet animals: 600 (total <sup>b</sup> ) Other species: 750 (total <sup>b</sup> )	Iron(II) fumarate may be placed on the market and used as an additive consisting of a preparation. The additive shall be incorporated into feed in the form of

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are currently no known outstanding effects for the	2
Commission Implementing Regulation (EU) 2017/2330. (See end of Document for de	tails)

feed					a
additive					premixture.
	titration				•
	with			3.	For
	cerium				users
	sulphate (Ph.				of
	Eur				the
	Monograph (	1902)			additive
For the	intonographi e	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			and
quantifi	ration				premixtures,
of total	Cution				feed
iron					business
in the					operators
feed					shall
additive					establish
and					operational
premixt	ures.				procedures
	Atomic				and
	Absorption				appropriate
	Spectrometry	,			organisational
	AAS	2			measures
	(EN				to
	ISO 6869);				address
	or				the
	Inductively				potential
	Coupled				risks
	Plasma				by
					inhalation,
	Atomic				dermal
	Emission				contact
	Spectrometry	,			or
	ICP-	2			eyes
	AES				contact.
	(EN				Where
	15510);				risks
	or				cannot
	Inductively				be
	Coupled				reduced
	Plasma				to
					an
	Atomic				acceptable
	Emission				level
	Spectrometry	,			by
	after				these
	pressure				procedures
	digestion,				and
	ICP-				measures,
					the
					additive
	· · · ·	1			

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

		AES			and
		(CEN/			premixtures
		TS			shall
		15621).			be
	For the	15021).			used
		ation			
	quantific	ation			with
	of total				appropriate
	iron in				personal
	feed				protective
	materials	5			equipment.
	and				
	compour	nd			
	feed:				
		Atomic			
		Absorpti	ion		
		Spectron			
		AAS	neu y,		
		(Commi	aion		
		Regulati	on		
		(EC)			
		No			
		152/200			
		Annex I	V-		
		C);			
		or			
	—	Atomic			
		Absorpti	ion		
		Spectron			
		AAS	5,		
		(EN			
		ISO 686	9)·		
		or	,		
		Inductiv	elv		
		Coupled			
		Plasma			
		Plasina			
		<u> </u>			
		Atomic			
		Emission			
		Spectron	netry,		
		ICP-			
		AES			
		(EN			
		15510)			
		or			
		Inductiv	elv		
		Coupled			
		Plasma			
		i iusiiiu			

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

Changes to legislation: There are a	currently no known outs	tanding effects for the
Commission Implementing Regulation (	EU) 2017/2330. (See en	d of Document for details)

			- Atomic Emission Spectror after pressure digestion ICP- AES (CEN/ TS 15621).	netry			
3b106	Iron(II) chelate of amino acids hydrate	Additive composit Iron(II) amino acid complex where the iron and the amino acids derived from soya protein are chelated via coordina covalent bonds, as a powder with a minimum content of 9 % iron. <i>Characte</i> of the active substanc Chemica formula: 3	tiannimal species te n erisation e: 1		Ovine: 500 (total <sup>b</sup> ) Bovines and poultry: 450 (total <sup>b</sup> ) Piglets up to one week before weaning 250 mg/ day (total <sup>b</sup> ) Pet animals: 600 (total <sup>b</sup> ) Other species: 750 (total <sup>b</sup> )	1.	4 January Shotate of amino acids may be placed on the market and used as an additive consisting of a preparation. The additive shall be incorporated into feed in the form of a premixture.

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

1	nH <sub>2</sub> O,				3.	For
	x =				3.	
	anion					users of
	of any					the
	amino					additive
	acid					and
t	from					
5	soya					premixtures, feed
	protein					business
	hydrolysa	ite.				
	Maximun	1				operators shall
	of 10 %					establish
	of the					operational
	molecules					procedures
	exceeding	5				and
	1 500					appropriate
	Da.					organisational
	Analytica					measures
	methods <sup>*</sup> :					to
	For the					address
	quantifica	tion				the
	of					potential
	amino					risks
	acid					by
	content					inhalation,
	in the					dermal
	feed					contact
	additive:					or
		ion				eyes
		exchang				contact.
		chromate				Where
		combine	a			risks
		with				cannot
		post-				be
		column ninhydri	n			reduced
		derivatis				to
		and	auon			an
		photome	tric			acceptable
		detection				level
		(Commi				by
		Regulati				these
		(EC)	011			procedures
		No				and
		152/2009	9			measures,
		Annex	,			the
						additive
						and
						premixtures

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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

Changes to legislation: There are currently no known outstanding effects for the	2
Commission Implementing Regulation (EU) 2017/2330. (See end of Document for de	etails)

	For the quantific of total iron in the feed additive and premixtu		netry, 9); ely				shall be used with appropriate personal protective equipment.
		Plasma					
		- Atomic Emission Spectron ICP- AES (EN 15510); or	netry,				
	_	Inductive Coupled Plasma					
		- Atomic Emission Spectron after pressure digestion ICP-	netry				
		AES (CEN/					
		TS 15621).					
	For the						
	quantific	ation					
1 64 1	 .1.1.1			64 D 6	<b>T</b> 1 (	1	1

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

Changes to legislation: There are	currently no know	wn outstanding effects for the
Commission Implementing Regulation	(EU) 2017/2330.	(See end of Document for details)

of total				
iron in				
feed				
materials	<b>&gt;</b>			
and				
compour	hd			
feed:				
iccu.	Atomic			
	Absorptio	on		
	Spectrom	netry,		
	AAS	-		
	(Commis	sion		
	Regulatio	51011		
	Regulatio			
	(EC)			
	No			
	152/2009	)		
	Annex IV			
	C);			
	or			
	Atomic			
	Absorptio	on		
	Spectrom	netrv		
	AAS	icu y,		
	(EN			
	ISO 6869	9);		
	or			
	Inductive	lv		
	Counted	JI Y		
	Coupled			
	Plasma			
	-			
	Atomic			
	Emission			
	Spectrom	ietry,		
	IĈP-			
	AES			
	(EN			
	15510)			
	or			
	Inductive	ely		
	Coupled			
	Plasma			
	Atomic			
	Emission	L		
	Spectrom	netry		
	after	-		
	pressure			
	pressure			

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are currently no known outstanding e	ffects for the
Commission Implementing Regulation (EU) 2017/2330. (See end of Doct	ument for details)

3b107	Iron(II) chelate of protein hydrolys	protein hydrolys as a powder with a minimur content of 10 % iron.	<i>tiann</i> imal species ates	h, 	Ovine: 500 (total <sup>b</sup> ) Bovines and poultry: 450 (total <sup>b</sup> ) Piglets up to one week before weaning	1.	4 Jum (II) she ate of protein hydrolysates may be placed on the market and used as
		iron. Minimur	m		weaning	-	used as
		of 50 %	11		250 mg/ day		an additive
		iron chelated			(total <sup>b</sup> )		consisting
		Characte			Pet animals:		of
		of the			600		a preparation.
		active			(total <sup>b</sup> )		
		<i>substanc</i> Chemica			Other	2.	The
		formula:			species:		additive shall
		3 .			750		be
		nH <sub>2</sub> O,			(total <sup>b</sup> )		incorporated
		x =					into
		anion					feed
		of any					in
		amino acid					the form
		from					of
		soya					a
		protein					premixture.
		hydrolys Analytic				3.	For
		methods					users
		For the					of
		quantific	ation				the
		of					additive and
		protein					and

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

**c** 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]

hydrolysates       premixtures,         content       feed         in the       business         feed       shall         additive:       shall         —       ion         exchange       operations         chromatography       procedures         commed       and         with       appropriate         post-       organisational         column       measures         ninhydrin       to         derivatisation       address         and       the         photometric       potential         detection       risks         (Commission       by         Regulation       contact         (EC)       contact         S22009,       or         Annex       eyes         III,       contact.         F),       Where         risks       risks         of the       reduced         of the       reduced         in the       level         feed       by         additive:       these         Transformed       and         in frared       me			
content in the feed additive:feed business operators shall establish establish operators shall post- combined with post- column derivatisation and the secures derivatisation and the secures the secures and the contact to or or annex HI, For the qualitative verification of the contactfeed an an acceptable level by these procedures and these procedures and these hy these procedures and these hy these procedures and these hy these	hydroly	sates	premixtures,
feed additive:     operators shall establish operational procedures and appropriate organisational measures inhydrin derivatisation and photometric detection (Commission and photometric detection (Commission Regulation (EC) No     operators shall establish operational procedures and appropriate organisational measures to derivatisation and photometric detection (Commission Regulation (EC) No     address address address inhalation, dermal column inhalation, dermal column inhalation, dermal detection (EC)       No     or contact     risks contact       For the qualitative verification of the chelation in the feed additive:     or contact       For the qualitative verification of the chelation in the feed additive:     an acceptable level by these procedures and an acceptable level by these procedures and infrared (FTIR) spectroscopy followed by multivariate regression methods (to to     used with appropriate			
additive:       shall	in the		business
additive:       shall         -       ion         exchange       operational         chromatography       and         combined       appropriate         with       appropriate         post-       organisational         column       measures         ninhydrin       to         derivatisation       address         and       the         photometric       potential         detection       risks         (Commission       by         Regulation       eyes         No       contact         152/2009,       or         Annex       eyes         III,       contact         For the       crasho         qualitative       verification         of the       reduced         iron       in the         iron       an         iron       and         in the       level         feed       by         additive       and         iron       and         iron       measures,         feed       by         additive       and      <	feed		operators
—       ion       exchange       operational         chromatography       procedures       and         combined       and       appropriate         with       post-       organisational         column       measures       to         ninhydrin       to       address         and       the       potential         risks       (Commission       by         Regulation       inhalation,       (EC)         No       contact       eyes         III,       F).       Where         For the       qualitative       contact.         verification       to       an         of the       cannot       be         chelation       to       an         of the       cannot       be         chelation       to       an         additive:       —       Fourier       procedures         additive:       —       Fourier       procedures         additive:       —       Fourier       procedures         and       infrared       measures,       the         infrared       followed       and       premixtures         by	additive		~
exchange chromatography combined with post- column ninhydrin derivatisation and column ninhydrin derivatisation and derivatisation and derivatisation and derivatisation and derivatisation and derivatisation and photometric detection (Commission Regulation (EC) No 152/2009, Annex For the qualitative For the qualitative verification of the chelationoperational procedures and botometric detection (EC) No tornate contact F).operational or or the contact <br< td=""><td></td><td></td><td></td></br<>			
chromatography combined with post- column ninhydrin derivatisation and derivatisation and derivatisation and he photometric deterivatisation and photometric deterivatisation and derivatisation and photometric deterivatisation and photometric deterivatisation and photometric deterivatisation and definition detrivatisation and photometric deterivatisation and photometric deterivatisation and detrivatisation and definition detrivatisation and photometric deterivatisation and detrivatisation and detrivatisation and detrivatisation and detrivatisation and detrivatisation and the photometric detrivatisation and detrivatisation and the photometric detrivatisation and too <b< td=""><td></td><td></td><td></td></b<>			
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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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

**c** 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]

<b>Changes to legislation:</b> There are currently no known outstanding effects for the	
Commission Implementing Regulation (EU) 2017/2330. (See end of Document for details)	1

	updated by	protective equipment.
	EURL) <sup>e</sup> .	
For the		
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of total		
iron		
in the		
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	Atomic	
	Absorption Spectrometry,	
	AAS	
	(EN	
	ISO 6869);	
	or	
	Inductively	
	Coupled	
	Plasma	
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	Atomic	
	Emission	
	Spectrometry,	
	ICP-	
	AES	
	(EN	
	15510);	
	or	
	Inductively	
	Coupled	
	Plasma	
	-	
	Atomic	
	Emission	
	Spectrometry	
	after	
	pressure	
	digestion,	
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	AES	
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	TS	
	15621).	
Details of the analytical methods are availabl jrc/en/eurl/feed-additives/evaluation-reports	e at the following address of the Reference Laboratory: http://	s://ec.europa.eu/

a jrc/en/eurl/feed-additives/evaluation-reports

The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed. b

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**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are	currently no known o	outstanding effects for the
Commission Implementing Regulation (	(EU) 2017/2330. (Se	e end of Document for details)

3b108	Iron(II) chelate of glycine hydrate	Additive composit Iron(II) chelate of glycine, hydrate, as a powder with a minimum	<i>iam</i> imal species	l, 	Ovine: 500 (total <sup>b</sup> ) Bovines and poultry: 450 (total <sup>b</sup> ) Piglets up to one	1.	4 Junially 2holate of glycine hydrate may be placed on the
		content of 15 % iron. Moisture maximum 10 %. Characte of the active substance Chemica formula: $\cdot$ nH <sub>2</sub> O, x =	: n <i>risation</i> e: l		one week before weaning 250 mg/ day (total <sup>b</sup> ) Pet animals: 600 (total <sup>b</sup> ) Other species: 750 (total <sup>b</sup> )	2.	market and used as an additive consisting of a preparation. The additive shall be
		anion of glycine. Analytica methods <sup>*</sup> For the quantific of the glycine content in the feed additive:	:			3.	incorporated into feed in the form of a premixture. For users of the

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

		ion			I	additive
		exchang				and
		chromate combine				premixtures, feed
			a			
		with				business
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		ninhydri				establish
		derivatis	ation			operational
		and				procedures
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		detection				appropriate
		(Commi				organisational
		Regulati	on			measures
		(EC)				to
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		ISO 686	<u>.</u>			level
			9),			
		or In du stire	-1			by
	_	Inductiv				these
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		-				measures,
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		Emission				additive
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		ICP-				premixtures
		AES				shall
		(EN				be
						used

**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are currently no known outstanding effects for the	e
Commission Implementing Regulation (EU) 2017/2330. (See end of Document for d	etails)

	15510); or Inductive Coupled Plasma			with appropriate personal protective equipment.
	Atomic Emission Spectron after pressure	netry		
	digestion ICP- AES (CEN/ TS 15621).	1,		
For the quantific of total iron in feed				
materials and compour feed:				
	Absorpti Spectron AAS (Commis	netry, ssion		
	Regulati (EC) No 152/2009 Annex Γ	9,		
_	C); or Atomic Absorpti Spectron	on netry,		
	AAS (EN ISO 686 or Inductive Coupled	ely		

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

			Plasma – Atomic Emission Spectron ICP- AES (EN 15510) or Inductive Coupled Plasma – Atomic Emission Spectron after pressure digestion ICP- AES (CEN/ TS	netry, ely n netry			
3b110	Iron dextran 10 %	<i>composit</i> Colloida aqueous solution of iron dextran with 25 % iron dextran (10 % total iron, 15 % dextran), 1,5 % sodium chloride, 0,4 % phenol and	l,		of the Refere	200 mg/ day once in the first week of life and 300 day once in the second week of life	4 Falfuary 2828 of the additive, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks

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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are currently no known outstanding effect	s for the
Commission Implementing Regulation (EU) 2017/2330. (See end of Document	<i>it for details)</i>

	Iron Dez	ion tish urmacopeia n ktran nographs.		2.	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. Indicate in the instructions of use: 'The additive shall be fed only individually directly
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**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

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**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** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

<b>Changes to legislation:</b> There are currently no known outstanding effects for the	?
Commission Implementing Regulation (EU) 2017/2330. (See end of Document for de	tails)

		Spectrometry,		
		AAS		
		(Commission		
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		(EC)		
		(EC)		
		No		
		152/2009,		
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		C);		
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	—			
		Absorption		
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		15510)		
		or		
		Inductively		
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		(CEN/		
		TS		
		15621).		
 		·		

**b** The amount of inert iron is not to be taken into consideration for the calculation of the total iron content of the feed.

- (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).
- (5) EFSA Journal 2013;11(7):3287.
- (6) EFSA Journal 2014;12(2):3566.
- (7) EFSA Journal 2014;12(3):3607.
- (8) EFSA Journal 2015;13(5):4109.
- (9) EFSA Journal 2016;14(2):4396.
- (10) EFSA Journal 2017;15(2):4701.
- (11) EFSA Journal 2016;14(6):4508.

# Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2330.