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⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1490

of 21 August 2017

concerning the authorisation of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide as feed additives for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The manganese compounds manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate were authorised without a time limit by Commission Regulations (EC) No 1334/2003 ⁽³⁾ and (EC) No 479/2006 ⁽⁴⁾ in accordance with Directive 70/524/EEC. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the re-evaluation of manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as feed additives for all animal species. Additionally, in accordance with Article 7 of that Regulation, an application was submitted for manganese hydroxychloride as feed additive for all animal species. The applicants requested that those additives be classified in the additive category 'nutritional additives'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 23 October 2014 ⁽⁵⁾, 23 October 2014 ⁽⁶⁾, 19 March 2015 ⁽⁷⁾, 18 February 2016 ⁽⁸⁾ and 13 May 2016 ⁽⁹⁾ that, under the proposed

⁽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(8):3324.⁽⁶⁾ EFSA Journal 2013;11(8):3325.⁽⁷⁾ EFSA Journal 2013;11(10):3435.⁽⁸⁾ EFSA Journal 2016;14(2):4395.⁽⁹⁾ EFSA Journal 2016;14(5):4474.

conditions of use, manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide do not have an adverse effect on animal health, consumer safety and the environment. Due to scientific considerations, the Authority recommended to rename manganous oxide as manganese (II) oxide and manganese hydroxychloride as dimanganese chloride trihydroxide, in order to avoid potential misunderstandings. The Authority also recommended splitting manganese chelate of amino acids into the following two groups, in view of its chemical characteristics: manganese chelate of amino acids hydrate and manganese chelate of protein hydrolysates.

- (5) The Authority noted that handling manganese (II) oxide is hazardous by inhalation to the user. In the absence of adequate data, the additive should be considered as a potential skin and eye irritant and as a dermal sensitiser. The Authority also noted that handling manganous sulphate monohydrate poses a risk to users upon inhalation exposure and is an eye irritant. It was also observed that handling manganese chelate of amino acids hydrate poses a possible hazard to the respiratory tract and the health of users. In the absence of adequate data regarding irritancy to the skin and eyes and dermal sensitisation, this latter additive should also be considered as a potential skin and eye irritant and as a skin and respiratory sensitiser. With respect to manganese chelate of glycine hydrate, the Authority noted that this additive may irritate skin and eyes. Finally, in the absence of specific data, the Authority could not conclude on the safety for the user when handling dimanganese chloride trihydroxide. Consequently, appropriate protective measures should be taken with respect to the additives concerned, in order to avoid that safety concerns for the users would arise.
- (6) The Authority further concluded that manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide are effective sources of manganese. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of manganous chloride tetrahydrate, manganese (II) oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate, manganese chelate of protein hydrolysates, manganese chelate of glycine hydrate and dimanganese chloride trihydroxide shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied, except for water for drinking. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation and their use via water for drinking should be denied.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as authorised by Regulation (EC) No 1831/2003, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Article 2

Denial

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

*Article 3***Transitional measures**

1. The substances manganous chloride tetrahydrate, manganous oxide, manganous sulphate monohydrate, manganese chelate of amino acids hydrate and manganese chelate of glycine hydrate as authorised by Regulations (EC) No 1334/2003 and (EC) No 479/2006, and premixtures containing those substances, which are produced and labelled before 11 March 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 11 September 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 11 September 2019 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

*Article 4***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 21 August 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			

Category of nutritional additives. Functional group: compounds of trace elements

3b501	—	Manganous chloride tetrahydrate	<i>Additive composition</i> Manganous chloride tetrahydrate, as a powder, with a minimum content of 27 % manganese. <i>Characterisation of the active substance</i> Manganous chloride tetrahydrate Chemical formula: $\text{MnCl}_2 \cdot 4\text{H}_2\text{O}$ CAS Number: 13446-34-9 <i>Analytical methods ⁽¹⁾</i> For the identification reactions of 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 total manganese 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	All animal species	—	—	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Manganous chloride tetrahydrate may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. 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.	11 September 2027
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Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621); For the quantification of total manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (Commission Regulation (EC) No 152/2009 ⁽²⁾, 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).						
3b502	—	Manganese (II) oxide	<i>Additive composition</i> Manganous oxide, as a powder, with a minimum content of 60 % manganese; Minimum content of 77,5 % MnO and a maximum content of 2 % MnO₂ <i>Characterisation of the active substance</i> Manganous oxide Chemical formula: MnO CAS Number: 1344-43-0	All animal species	—	—	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Manganese (II) oxide may be placed on the market and used as an additive consisting of a preparation.	11 September 2027

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<i>Analytical methods</i> ⁽¹⁾ For the crystallographic characterisation of the feed additive: — X-Ray diffraction; For the quantification of total manganese 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); For the quantification of total manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (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).					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, in particular due to the content of heavy metals including nickel. 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 (Mn) in mg/kg of complete feed with a moisture content of 12 %			
3b503	—	Manganous sulphate monohydrate	<i>Additive composition</i> Manganous sulphate monohydrate, as a powder, with a minimum content of 95 % manganous sulphate monohydrate and of 31 % manganese. <i>Characterisation of the active substance</i> Manganous sulphate monohydrate Chemical formula: $\text{MnSO}_4 \cdot \text{H}_2\text{O}$ CAS Number: 10034-96-5 <i>Analytical methods ⁽¹⁾</i> For the quantification of the manganous sulphate monohydrate in the feed additive: — titration with ammonium and cerium nitrate (Ph. Eur Monograph 1543); For the identification reactions of sulphates 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 manganese 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	All animal species	—	—	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Manganous sulphate monohydrate may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. 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.	11 September 2027

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			— Inductively Coupled Plasma — Atomic Emission Spectrometry after pressure digestion, ICP-AES (CEN/TS 15621); For the quantification of total manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (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).						
3b504	—	Manganese chelate of amino acids hydrate	<i>Additive composition</i> Manganese amino acid complex where the manganese and the amino acids derived from soya protein are chelated via coordinate covalent bonds, as a powder with a minimum content of 8 % manganese. <i>Characterisation of the active substance</i> Chemical formula: $Mn(x)_{1-3} \cdot nH_2O$, x = anion of any amino acid derived from acid hydrolysed soya protein; Maximum of 10 % of the molecules exceeding 1 500 Da.	All animal species	—	—	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Manganese chelate of amino acids hydrate may be placed on the market and used as an additive consisting of a preparation.	11 September 2027

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<i>Analytical methods</i> ⁽¹⁾ For the quantification of amino acid content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III, F); For the quantification of total manganese 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); For the quantification of total manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (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).					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, in particular due to the content of heavy metals including nickel. 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 (Mn) in mg/kg of complete feed with a moisture content of 12 %			
3b505	—	Manganese chelate of protein hydrolysates	<i>Additive composition</i> Manganese chelate of protein hydrolysates as a powder with a minimum content of 10 % manganese. Minimum of 50 % manganese chelated. <i>Characterisation of the active substance</i> Chemical formula: $Mn(x)_{1-3} \cdot nH_2O$, x = anion of protein hydrolysates containing any amino acid from soya protein hydrolysate. <i>Analytical methods</i> ⁽¹⁾ For the quantification of protein hydrolysates content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III, F); For the determination of chelated manganese content in the feed additive: — Fourier Transformed Infrared (FTIR) spectroscopy followed by multivariate regression methods. For the quantification of total manganese in the feed additive and premixtures: — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or	All animal species	—	—	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Manganese chelate of protein hydrolysates may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. 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.	11 September 2027

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			— 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 manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (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).						
3b506	—	Manganese chelate of glycine hydrate	<i>Additive composition</i> Manganese chelate of glycine, hydrate, as a powder with a minimum content of 15 % manganese. Moisture: maximum 10 %. <i>Characterisation of the active substance</i> Chemical formula: $Mn(x)_{1-3} \cdot nH_2O$, x = anion of glycine.	All animal species	—	—	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Manganese chelate of glycine hydrate may be placed on the market and used as an additive consisting of a preparation.	11 September 2027

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			<i>Analytical methods</i> ⁽¹⁾ For the quantification of the glycine content in the feed additive: — ion exchange chromatography combined with post-column ninhydrin derivatisation and photometric detection (Regulation (EC) No 152/2009, Annex III, F); For the quantification of total manganese 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); For the quantification of total manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (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).					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, in particular due to the content of heavy metals including nickel. 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 (Mn) in mg/kg of complete feed with a moisture content of 12 %			
3b507	—	Dimanganese chloride trihydroxide	<i>Additive composition</i> Granulate powder with a minimum content of 44 % manganese and a maximum content of 7 % manganese oxide <i>Characterisation of the active substance</i> Dimanganese chloride trihydroxide Chemical formula: $\text{Mn}_2(\text{OH})_3\text{Cl}$ CAS Number: 39438-40-9 <i>Analytical methods</i> ⁽¹⁾ For the identification of the crystallographic characterisation of the feed additive: — X-Ray diffraction; For the quantification of chlorine in the feed additive: — Titration — Regulation (EC) No 152/2009; For the quantification of total manganese 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	—	—	Fish: 100 (total) Other species: 150 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. Dimanganese chloride trihydroxide may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. 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.	11 September 2027

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mn) in mg/kg of complete feed with a moisture content of 12 %			
			For the quantification of total manganese in feed materials and compound feed: — Atomic Absorption Spectrometry, AAS (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).						

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

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1491**of 21 August 2017****renewing the approval of the active substance 2,4-DB in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2003/31/EC ⁽²⁾ included 2,4-DB as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance 2,4-DB, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2017.
- (4) An application for the renewal of the approval of 2,4-DB was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (hereinafter 'the Authority') and the Commission on 3 June 2015.
- (7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 13 May 2016, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether 2,4-DB can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for 2,4-DB to the Standing Committee on Plants, Animals, Food and Feed on 18 May 2017.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2003/31/EC of 11 April 2003 amending Council Directive 91/414/EEC to include 2,4-DB, beta-cyfluthrin, cyfluthrin, iprodione, linuron, maleic hydrazide and pendimethalin as active substances (OJ L 101, 23.4.2003, p. 3).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

⁽⁶⁾ EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance 2,4-DB. *EFSA Journal* 2016;14(5):4500. Available online: www.efsa.europa.eu

- (9) The applicant was given the opportunity to submit comments on the draft renewal report.
- (10) It has been established with respect to one or more representative uses of at least one plant protection product containing 2,4-DB that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of 2,4-DB.
- (11) The risk assessment for the renewal of the approval of 2,4-DB is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing 2,4-DB may be authorised. It is therefore appropriate to remove the restriction for use only as a herbicide.
- (12) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (13) Commission Implementing Regulation (EU) 2016/950 ⁽¹⁾ extended the approval period of 2,4-DB to 31 October 2017 in order to allow the renewal process to be completed before the expiry of the approval of that substance.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance 2,4-DB is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 November 2017.

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

Done at Brussels, 21 August 2017.

For the Commission

The President

Jean-Claude JUNCKER

⁽¹⁾ Commission Implementing Regulation (EU) 2016/950 of 15 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-DB, beta-cyfluthrin, carfentrazone ethyl, *Coniothyrium minitans* Strain CON/M/91-08 (DSM 9660), cyazofamid, deltamethrin, dimethenamid-P, ethofumesate, fenamidone, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mesotrione, oxasulfuron, pendimethalin, picoxystrobin, silthiofam and trifloxystrobin (OJ L 159, 16.6.2016, p. 3).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
2,4-DB CAS No 94-82-6 CIPAC No 83	4-(2,4-dichlorophenoxy) butyric acid	≥ 940 g/kg Impurities: Free phenols (expressed as 2,4-dichlorophenol (2,4-DCP)): max. 15 g/kg. Dibenzo-p-dioxins and polychlorinated dibenzofurans (TCDD toxic equivalents (TEQ)): max. 0,01 mg/kg.	1 November 2017	31 October 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,4-DB, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, — the protection of consumers from products of animal origin, — the protection of wild mammals, — the protection of soil non-target organisms, — the protection of aquatic organisms, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, the entry 47 on 2,4-DB is deleted;

(2) in Part B, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'116	2,4-DB CAS No 94-82-6 CIPAC No 83	4-(2,4-dichlorophenoxy) butyric acid	≥ 940 g/kg Impurities: Free phenols (expressed as 2,4-dichlorophenol (2,4-DCP)): max. 15 g/kg. Dibenzo- <i>p</i> -dioxins and polychlorinated dibenzofurans (TCDD toxic equivalents (TEQ)): max. 0,01 mg/kg.	1 November 2017	31 October 2032	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 2,4-DB, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, — the protection of consumers from products of animal origin, — the protection of wild mammals, — the protection of soil non-target organisms, — the protection of aquatic organisms, — the protection of non-target terrestrial plants. Conditions of use shall include risk mitigation measures, where appropriate.'

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1492
of 21 August 2017
concerning the authorisation of cholecalciferol as a feed additive for all animal species
(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) Cholecalciferol was authorised without a time limit by Directive 70/524/EEC as a feed additive for all animal species. That additive was subsequently entered in the Register of feed additives as an existing product, 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, three applications were submitted for the re-evaluation of cholecalciferol as a feed additive for all animal species and, in accordance with Article 7 of that Regulation, for the use in water for drinking. The applicants requested that additive to be classified in the additive category 'nutritional additives'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 13 November 2012 ⁽³⁾, 20 June 2013 ⁽⁴⁾, 30 January 2014 ⁽⁵⁾ and 25 January 2017 ⁽⁶⁾ that, under the proposed conditions of use in feed, cholecalciferol does not have adverse effects on animal health, human health or the environment. The Authority further concluded that cholecalciferol is an effective source of vitamin D₃.
- (5) The Authority concluded in its opinions that for some formulations of vitamin D₃ there is a potential for workers to be exposed to high levels of vitamin D₃ by inhalation. Inhaled vitamin D₃ is highly toxic and exposure to dust is harmful. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of cholecalciferol 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 that substance should be authorised in feed as specified in the Annex to this Regulation. Maximum contents should be set for cholecalciferol. Cholecalciferol should not be administered directly via water for drinking because an additional route of administration would increase the risk for consumers and animals. Therefore, the authorisation of cholecalciferol as nutritional additive belonging to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect' should be denied as regards their use in water. This prohibition does not apply to this substance when is used within compound feeds which are subsequently administered via water.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of cholecalciferol it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2012;10(12):2968.

⁽⁴⁾ EFSA Journal 2013;11(7):3289.

⁽⁵⁾ EFSA Journal 2014;12(2):3568.

⁽⁶⁾ EFSA Journal 2017;15(3):4713.

- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, provitamins and chemically well-defined substances having similar effect', is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Denial

Authorisation of cholecalciferol, as an additive belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, provitamins and chemically well-defined substances having similar effect', is denied for its use in water for drinking.

Article 3

Transitional Measures

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 11 March 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 11 September 2018 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 11 September 2019 in accordance with the rules applicable before 11 September 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 4

Entry into Force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 21 August 2017.

For the Commission
The President
Jean-Claude JUNCKER

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
						IU or mg of cholecalciferol ⁽¹⁾ /kg of complete feedingstuff with a moisture content of 12 %.			
Category of nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect									
3a671	—	'Cholecalciferol' or 'Vitamin D ₃ '	Additive composition	Pigs			2 000 IU 0,05 mg	1. Vitamin D ₃ may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 4. Maximum content of the combination of 25-hydroxycholecalciferol with cholecalciferol per kg of complete feedingstuff: — ≤ 0,125 mg ⁽¹⁾ (equivalent to 5 000 IU of vitamin D ₃) for chickens for fattening and turkeys for fattening, — ≤ 0,080 mg for other poultry, — ≤ 0,050 mg for pigs. 5. Simultaneous use with Vitamin D ₂ is not allowed.	11 September 2027
			Cholecalciferol.	Milk replacers for piglets			10 000 IU 0,25 mg		
			Characterisation of the active substance	Bovines			4 000 IU 0,1 mg		
			Cholecalciferol	Milk replacers for calves			10 000 IU 0,25 mg		
			C ₂₇ H ₄₄ O	Ovines			4 000 IU 0,1 mg		
			CAS number: 67-97-0	Chickens for fattening			5 000 IU 0,125 mg		
			Cholecalciferol solid and resin form, produced by chemical synthesis.	Turkeys			5 000 IU 0,125 mg		
			Purity criteria:	Other poultry			3 200 IU 0,080 mg		
			Min. 80 % (cholecalciferol and precholecalciferol) and max. 7 % tachysterol.	Equines			4 000 IU 0,1 mg		
			Method of analysis ⁽²⁾	Fish species			3 000 IU 0,075 mg		
			— For the determination of Vitamin D ₃ in the feed additive: High Performance Liquid Chromatography coupled to UV detection (HPLC-UV, 254 nm) — European Pharmacopoeia method 01/2008:0574,0575,0598.	Other species			2 000 IU 0,05 mg		

Identifica- tion number of the additive	Name of the holder of author- isation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authoris- ation
						IU or mg of cholecalci- ferol (¹)/kg of complete feedingstuff with a moisture content of 12 %.			
			— For the determination of Vitamin D₃ in premixtures: High Performance Liquid Chromatography coupled to UV detection at 265 nm (HPLC-UV)- VDLUFA 1997, Methodenbuch, Method 13.8.1. — For the determination of vitamin D₃ in feedingstuffs: — High Performance Liquid Chromatography coupled to UV detection at 265 nm (HPLC-UV)- VDLUFA 1997, Methodenbuch, Method 13.8.1; or — Reverse-Phase High Performance Liquid Chromatography coupled to UV detection at 265 nm (RP-HPLC-UV), EN 12821. — For the determination of vitamin D₃ in water: Reverse-Phase High Performance Liquid Chromatography coupled to UV detection at 265 nm (RP-HPLC-UV), EN 12821.					6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the very hazardous effects of vitamin D ₃ by inhalation. Where the risks associated to those very hazardous effects cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	

⁽¹⁾ 40 IU cholecalciferol= 0,001 mg cholecalciferol.

⁽²⁾ 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>

DECISIONS

DECISION (EU) 2017/1493 OF THE EUROPEAN CENTRAL BANK

of 3 August 2017

amending Decision ECB/2014/29 on the provision to the European Central Bank of supervisory data reported to the national competent authorities by the supervised entities pursuant to Commission Implementing Regulation (EU) No 680/2014 (ECB/2017/23)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to prudential supervision of credit institutions ⁽¹⁾, and in particular Article 6(2) thereof,

Having regard to Regulation (EU) No 468/2014 of the European Central Bank of 16 April 2014 establishing the framework for cooperation within the Single Supervisory Mechanism between the European Central Bank and national competent authorities and with national designated authorities (SSM Framework Regulation) (ECB/2014/17) ⁽²⁾, and in particular Article 21 and Article 140(4) thereof,

Having regard to the proposal of the Supervisory Board,

Whereas:

- (1) Decision ECB/2014/29 ⁽³⁾ stipulates rules for providing to the European Central Bank supervisory data reported to the national competent authorities by supervised entities pursuant to Commission Implementing Regulation (EU) No 680/2014 ⁽⁴⁾.
- (2) The European Commission has adopted on 14 September 2016 Commission Implementing Regulation (EU) 2016/2070 ⁽⁵⁾, which lays down reporting requirements for institutions permitted to use internal approaches for the calculation of risk-weighted exposure amounts or own funds requirements, except for operational risk. Those institutions are required to report the results of the calculations of their internal approaches for their exposures or positions that are included in the benchmark portfolios provided by the European Banking Authority.
- (3) Decision ECB/2014/29 should cover the information to be reported by supervised entities on the basis of Implementing Regulation (EU) 2016/2070.
- (4) Therefore, Decision ECB/2014/29 should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Amendments

Decision ECB/2014/29 is amended as follows:

1. the title is replaced by the following:

‘Decision of the European Central Bank of 2 July 2014 on the provision to the European Central Bank of supervisory data reported to the national competent authorities by the supervised entities pursuant to Commission Implementing Regulations (EU) No 680/2014 and (EU) 2016/2070 (ECB/2014/29) (2014/477/EU)’;

⁽¹⁾ OJ L 287, 29.10.2013, p. 63.

⁽²⁾ OJ L 141, 14.5.2014, p. 1.

⁽³⁾ Decision ECB/2014/29 of 2 July 2014 on the provision to the European Central Bank of supervisory data reported to the national competent authorities by the supervised entities pursuant to Commission Implementing Regulation (EU) No 680/2014 (OJ L 214, 19.7.2014, p. 34).

⁽⁴⁾ Commission Implementing Regulation (EU) No 680/2014 of 16 April 2014 laying down implementing technical standards with regard to supervisory reporting of institutions according to Regulation (EU) No 575/2013 of the European Parliament and of the Council (OJ L 191, 28.6.2014, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) 2016/2070 of 14 September 2016 laying down implementing technical standards for templates, definitions and IT-solutions to be used by institutions when reporting to the European Banking Authority and to competent authorities in accordance with Article 78(2) of Directive 2013/36/EU of the European Parliament and of the Council (OJ L 328, 2.12.2016, p. 1).

2. Article 1 is replaced by the following:

Article 1

Scope

Pursuant to Article 21 of the SSM Framework Regulation, this Decision lays down procedures concerning the submission to the ECB of data reported to the national competent authorities by the supervised entities on the basis of Implementing Regulation (EU) No 680/2014 and Commission Implementing Regulation (EU) 2016/2070 (*).

(*) Commission Implementing Regulation (EU) 2016/2070 of 14 September 2016 laying down implementing technical standards for templates, definitions and IT-solutions to be used by institutions when reporting to the European Banking Authority and to competent authorities in accordance with Article 78(2) of Directive 2013/36/EU of the European Parliament and of the Council (OJ L 328, 2.12.2016, p. 1).;

3. Article 3 is replaced by the following:

Article 3

Remittance dates

1. National competent authorities shall submit to the ECB the data referred to in Article 1 and reported to them by the supervised entities on the following remittance dates:

(1) by 12 noon Central European Time (CET) (*) on the 10th working day following the relevant remittance dates referred to in Implementing Regulation (EU) No 680/2014 and Article 4 of Implementing Regulation (EU) 2016/2070 with respect to:

- (a) significant supervised entities reporting at the highest level of consolidation within the participating Member States;
- (b) significant supervised entities that are not part of a supervised group;
- (c) supervised entities which are classified as significant in accordance with the three most significant credit institutions criterion in their Member State and which report on a consolidated basis or on an individual basis, if they are not required to report on a consolidated basis;
- (d) other supervised entities reporting on a consolidated basis or on an individual basis, if they are not required to report on a consolidated basis, which are included in the list of institutions covered by the reporting to the European Banking Authority (EBA) in accordance with Article 2 of Decision EBA/DC/2015/130 of the European Banking Authority (**) and Article 2 of Decision EBA/DC/2016/156 of the European Banking Authority (**);

(2) by close of business on the 25th working day following the relevant remittance dates referred to in Implementing Regulation (EU) No 680/2014 and Article 4 of Implementing Regulation (EU) 2016/2070 with respect to:

- (a) significant supervised entities reporting on a consolidated and sub-consolidated basis insofar as these data have not been submitted in accordance with point (1);
- (b) significant supervised entities that are part of a supervised group reporting on an individual basis insofar as these data have not been submitted in accordance with point (1);
- (c) less significant supervised entities reporting at the highest level of consolidation within the participating Member States insofar as these data have not been submitted in accordance with point (1);
- (d) less significant supervised entities that are not part of a supervised group insofar as these data have not been submitted in accordance with point (1);

(4) by close of business on the 35th working day following the relevant remittance dates referred to in Implementing Regulation (EU) No 680/2014 and Article 4 of Implementing Regulation (EU) 2016/2070 with respect to:

- (a) less significant supervised entities reporting on a consolidated and sub-consolidated basis insofar as these data have not been submitted in accordance with points (1) and (2);

- (b) less significant supervised entities that are part of a supervised group reporting on an individual basis insofar as these data have not been submitted in accordance with point (1).

2. By derogation from paragraph 1, the national competent authorities shall submit to the ECB the data referred to in Article 5 of Implementing Regulation (EU) 2016/2070 on the following remittance dates:

(1) by 12 noon CET on the 10th working day following 11 November of each calendar year with respect to:

- (a) significant supervised entities reporting at the highest level of consolidation within the participating Member States;
- (b) significant supervised entities that are not part of a supervised group;
- (c) supervised entities which are classified as significant in accordance with the three most significant credit institutions criterion in their Member State and report on a consolidated basis or on an individual basis, if they are not required to report on a consolidated basis;
- (d) other supervised entities reporting on a consolidated basis or on an individual basis, if they are not required to report on a consolidated basis, that are included in the list of institutions covered by the reporting to the EBA in accordance with Article 2 of Decision EBA/DC/2016/156;

(2) by close of business on the 25th working day following 11 November of each calendar year with respect to:

- (a) significant supervised entities reporting on a consolidated and sub-consolidated basis insofar as these data have not been submitted in accordance with point (1);
- (b) significant supervised entities that are part of a supervised group reporting on an individual basis insofar as these data have not been submitted in accordance with point (1);
- (c) less significant supervised entities reporting at the highest level of consolidation within the participating Member States insofar as these data have not been submitted in accordance with point (1);
- (d) less significant supervised entities that are not part of a supervised group insofar as these data have not been submitted in accordance with point (1);

(3) by close of business on the 35th working day following 11 November of each calendar year with respect to:

- (a) less significant supervised entities reporting on a consolidated and sub-consolidated basis insofar as these data have not been submitted in accordance with points (1) and (2);
- (b) less significant supervised entities that are part of a supervised group reporting on an individual basis insofar as these data have not been submitted in accordance with point (1);

(*) CET takes account of the change to Central European Summer Time.

(**) Decision EBA/DC/2015/130 of the European Banking Authority of 23 September 2015 on reporting by competent authorities to the EBA. Available on the EBA's website at www.eba.europa.eu

(***) Decision EBA/DC/2016/156 of the European Banking Authority of 31 May 2016 on data for supervisory benchmarking. Available on the EBA's website at www.eba.europa.eu;

4. in Article 4, paragraph 1 is replaced by the following:

‘1. National competent authorities shall monitor and assess the quality and reliability of the data made available to the ECB. National competent authorities shall apply the relevant validation rules developed, maintained and published by the EBA. National competent authorities shall also apply the additional data quality checks defined by the ECB in cooperation with the national competent authorities.’;

5. in Article 6, paragraph 1 is replaced by the following:

‘1. National competent authorities shall submit the data specified in this Decision according to the relevant Data Point Model and eXtensible Business Reporting Language taxonomy, developed, maintained and published by the EBA.’;

6. the following Article 7a is inserted:

'Article 7a

First reporting following the taking effect of Decision (EU) 2017/1493 of the European Central Bank (ECB/2017/23)

1. National competent authorities shall submit the data reported to them pursuant to Implementing Regulation (EU) 2016/2070 in accordance with Decision (EU) 2017/1493 of the European Central Bank (ECB/2017/23) (*) beginning with the first remittance dates which occur after that Decision takes effect.

2. National competent authorities shall submit the data reported to them pursuant to Implementing Regulation (EU) No 680/2014 by institutions included in the list of institutions covered by the reporting to the EBA pursuant to Article 2 of Decision EBA/DC/2016/156 in accordance with Article 3(1)(1)(d) beginning with the first remittance dates which occur after Decision (EU) 2017/1493 (ECB/2017/23) takes effect.

(*) Decision (EU) 2017/1493 of the European Central Bank of 3 August 2017 amending Decision ECB/2014/29 on the provision to the European Central Bank of supervisory data reported to the national competent authorities by the supervised entities pursuant to Commission Implementing Regulation (EU) No 680/2014 (ECB/2017/23) (OJ L 216, 22.8.2017, p. 23).'

Article 2

Taking effect

This Decision shall take effect on the day of its notification to the addressees.

Article 3

Addressees

This Decision is addressed to the national competent authorities of the participating Member States.

Done at Frankfurt am Main, 3 August 2017.

The President of the ECB
Mario DRAGHI

