Official Journal of the European Union

L 304

English edition

Legislation

Volume 64

30 August 2021

Contents

[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.

The titles of all other acts are printed in bold type and preceded by an asterisk.

[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2021/1408

of 27 August 2021

amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain foodstuffs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ([1]), and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1881/2006 ([2]) sets maximum levels for certain contaminants, including tropane alkaloids, in foodstuffs.

(2) Atropine is the racemic mixture of (-)-hyoscyamine and (+)-hyoscyamine of which only the (-)-hyoscyamine enantiomer exhibits anticholinergic activity. It is not always possible to distinguish between the enantiomers of hyoscyamine, for analytical reasons. However, as the synthesis of tropane alkaloids in plants leads to (-)-hyoscyamine and (-)-scopolamine and not to (+)-hyoscyamine and (+)-scopolamine, analytical results on atropine and scopolamine in food of plant origin reflects the occurrence of (-)-hyoscyamine and (-)-scopolamine respectively.

(3) The European Food Safety Authority ('the Authority') adopted in 2013 an opinion on tropane alkaloids in food and feed ([3]). The Authority established a group acute reference dose ('ARfD') of 0.016 µg/kg per body weight ('b.w.') expressed as the sum of (-)-hyoscyamine and (-)-scopolamine, assuming equivalent potency. The Authority concluded that, based on the limited information available, the dietary exposure of toddlers could significantly exceed the group ARfD. It therefore highlighted the need for better characterisation of tropane alkaloids in food and feed, either naturally or as contaminants, and recommended compiling analytical data on the occurrence of tropane alkaloids in cereals and oilseeds.

(4) Taking into account the conclusions of the opinion, maximum levels for atropine and scopolamine were established by Commission Regulation (EU) 2016/239 ([4]) in processed cereal based foods and baby foods for infants and young children, containing millet, sorghum, buckwheat or their derived products.

([1]) OJ L 37, 13.2.1993, p. 1.

([2]) Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

([3]) Scientific Opinion on tropane alkaloids in food and feed. EFSA Journal 2013;11(10):3386, 113 pp. doi:10.2903/j.efsa.2013.3386.

([4]) Commission Regulation (EU) 2016/239 of 19 February 2016 amending Regulation (EC) No 1881/2006 as regards maximum levels of tropane alkaloids in certain cereal-based foods for infants and young children (OJ L 45, 20.2.2016, p. 3).

(5) The Authority published a call for proposals to investigate the concentrations of tropane alkaloids in a wide range of plant-derived food products across different regions within the Union, following the recommendation in its opinion from 2013. The investigation's findings were published on 8 December 2016 ([5]).

(6) On 5 February 2018, the Authority published a scientific report on the assessment of acute dietary exposure to tropane alkaloids in the Union population, taking into account new occurrence data ([6]). For several acute exposure estimates, the ARfD was exceeded for several population groups. This makes the presence of tropane alkaloids, in particular atropine and scopolamine, a health concern.

(7) Maximum levels of those tropane alkaloids should therefore be set for foodstuffs found to contain a high concentration of them and contributing significantly to the exposure of the population, namely certain cereals, products derived from them and herbal infusions. As regards, in particular, cereals and cereals products, good agricultural and harvesting practices minimise contamination of the crop by seeds of species containing tropane alkaloids, such as *Datura stramonium*. In case of contamination, those seeds can be removed for certain cereals by sorting and cleaning. However, they cannot easily be removed from sorghum, millet, maize and buckwheat. Given that the maximum levels for those foodstuffs are higher than the levels set out for foodstuffs for infants and young children, a maximum level for the sum of atropine and scopolamine may be set for each of those foods.

(8) Furthermore, recent monitoring data indicate that processed cereal based foods and baby foods for infants and young children containing maize or maize derived products can also be contaminated with tropane alkaloids. It is therefore appropriate to extend to these foods the existing maximum levels for processed cereal based foods and baby foods for infants and young children.

(9) Regulation (EC) No 1881/2006 should therefore be amended accordingly.

(10) Given that good agricultural and harvesting practices have only recently been introduced or implemented and in order to allow the food business operators to adapt to the new requirements set out in this Regulation while ensuring the protection of vulnerable populations, it is appropriate to provide, as regard foods other than foods for infants and young children containing maize, a reasonable period until the maximum levels start applying and for a transitional period for all foodstuffs which have been lawfully placed on the market before the date of its application.

(11) 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

The Annex to Regulation (EC) No 1881/2006 is amended in accordance with the Annex to this Regulation.

Article 2

Processed cereal-based foods and baby foods for infants and young children, containing maize or their derived products, lawfully placed on the market before the entry into force of this Regulation, may remain on the market until their date of minimum durability or use-by-date.

([5]) Mulder, PPJ., De Nijs, M., Castellari, M., Hortos, M., MacDonald, S., Crews, C., Hajslova, J. and Stranska, M., 2016. 'Occurrence of tropane alkaloids in food'. EFSA supporting publication 2016:EN-1140, 200 pp. doi:10.2903/sp.efsa.2016.EN-1140.

([6]) Arcella, D., Altieri, A., Horváth, Zs, 2018. 'Scientific report on human acute exposure assessment to tropane alkaloids'. EFSA Journal 2018;16(2):5160, 29 pp. doi:10.2903/j.efsa.2018.5160.

Foodstuffs listed in points 8.2.2. to 8.2.9. of the Annex, lawfully placed on the market before 1 September 2022, may remain on the market until their date of minimum durability or use-by-date.

Article 3

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Regulation (EC) No 1881/2006, section 8, entry 8.2 is replaced by the following:

'Foodstuffs [1]		Maximum level (µg/kg)	
8.2.	**Tropane alkaloids** (*)		
		Atropine	Scopolamine
8.2.1.	Processed cereal-based foods and baby foods for infants and young children, containing millet, sorghum, buckwheat, maize or their derived products ([3]) ([29])	1,0	1,0
		Sum of atropine and scopolamine	
8.2.2.	Unprocessed millet and sorghum ([18])	5,0 as from 1 September 2022	
8.2.3.	Unprocessed maize ([18]) with the exception of — unprocessed maize intended to be processed by wet milling ([37]) and — unprocessed maize for popping	15 as from 1 September 2022	
8.2.4.	Unprocessed buckwheat ([18])	10 as from 1 September 2022	
8.2.5.	Maize for popping Millet, sorghum and maize placed on the market for the final consumer Milling products of millet, sorghum and maize	5,0 as from 1 September 2022	
8.2.6.	Buckwheat placed on the market for the final consumer Milling products of buckwheat	10 as from 1 September 2022	
8.2.7.	Herbal infusions (dried product) with the exception of the herbal infusions referred to in 8.2.8.	25 as from 1 September 2022	
8.2.8.	Herbal infusions (dried product) of anise seeds	50 as from 1 September 2022	
8.2.9.	Herbal infusions (liquid)	0,20 as from 1 September 2022	

(*) The tropane alkaloids referred to are atropine and scopolamine.'

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1409

of 27 August 2021

concerning the authorisation of phytomenadione as a feed additive for horses

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of phytomenadione. ([2]) That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of phytomenadione as a feed additive for horses. The applicant requested this additive to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021 ([3]) that, under the proposed conditions of use, phytomenadione does not have adverse effects on animal health, consumer safety or the environment. The Authority concluded that users will not be exposed by inhalation when the additive is presented in solid form or viscous liquid. Data from the Scientific Committee on Consumer Safety indicates that vitamin K_1 can be categorised as a dermal sensitiser. For preparations, the Authority could not conclude on their potential to be toxic by inhalation or on their potential as skin/eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive and its preparations. The Authority concluded that phytomenadione is considered as an efficacious source of vitamin K_1 for horses, when added to feed. 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.

(5) The assessment of phytomenadione shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of phytomenadione should be authorised. 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

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Also known as vitamin K_1.
([3]) *EFSA Journal* 2021;19(4):6538

Article 2

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a712	'Phytomenadione' or 'Vitamin K_1'	**Additive composition** Preparation containing ≥ 4,2 % of phytomenadione. Solid form **Characterisation of active substance** 2-methyl-3-[(E,7R,11R)-3,7,11,15-tetramethylhexadec-2-enyl] naphthalene-1,4-dione Chemical formula: $C_{31}H_{46}O_2$ CAS number: 84-80-0 Purity: ≥ 97 % for the sum of E-phytomenadione, E-epoxyphytomenadione and Z-phytomenadione isomers Purity criteria: — ≥ 75 % E-phytomenadione; — ≤ 4 % E-epoxyphytomenadione Produced by chemical synthesis **Analytical method** (1) For the determination of phytomenadione in the feed additive: – High Performance Liquid Chromatography – European Pharmacopoeia (8.0, 01/2014:1036). For the determination of phytomenadione in the additive preparation and in complementary feed: – High Performance Liquid Chromatography with Fluorescence detection (HPLC-FLD)	Horses	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, skin and eye irritation and dermal sensitization, resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin, eyes and breathing protection.	19.9.2031

(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

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1410

of 27 August 2021

concerning the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds (holder of authorisation Huvepharma NV)

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Bacillus licheniformis* DSM 28710. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds, to be classified in the category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 January 2021 ([2]) that, under the proposed conditions of use, the preparation of *Bacillus licheniformis* DSM 28710 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that in the absence of data, no conclusions could be drawn on the skin/eye irritation or skin sensitisation potential of the additive, but that it is considered a respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the preparation of *Bacillus licheniformis* DSM 28710 has the potential to be efficacious as zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of *Bacillus licheniformis* DSM 28710 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of the product should be authorised as specified in the Annex to this Regulation.

(6) 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

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2021;19(3):6449.

Article 2

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers									
4b1828	Huvepharma NV	*Bacillus licheniformis* DSM 28710	**Additive composition** Preparation of *Bacillus licheniformis* DSM 28710 containing a minimum of: $3,2 \times 10^9$ CFU/g of additive Solid form **Characterisation of the active substance:** Viable spores of *Bacillus licheniformis* DSM 28710 **Analytical method** (1) For the enumeration of *Bacillus licheniformis* DSM 28710 in additive, premixture and feedingstuffs: — Spread plate method EN 15784 For the identification of Bacillus licheniformis DSM 28710: — Pulsed Field Gel Electrophoresis (PFGE)	Laying hens Minor poultry species for laying Poultry species for breeding except turkeys Ornamental birds	-	$1,6 \times 10^9$	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. May be used in feed containing the following permitted coccidiostats: diclazuril and lasalocid A sodium. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address hazards by inhalation, dermal contact or eyes contact. Where the dermal, inhalation or eyes exposure cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin, eyes and breathing protection.	19.9.2031

(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

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1411

of 27 August 2021

concerning the renewal of the authorisation of *Clostridium butyricum* FERM BP-2789 as a feed additive for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, its authorisation for chickens for fattening, suckling piglets and suckling minor porcine species, and repealing Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)

(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 and renewing such authorisation.

(2) The preparation of *Clostridium butyricum* FERM BP-2789 was authorised for 10 years as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) by Commission Implementing Regulation (EU) No 373/2011 ([2]), for chickens reared for laying by Commission Implementing Regulation (EU) No 374/2013 ([3]) and for turkeys for fattening and turkeys reared for breeding by Commission Implementing Regulation (EU) No 1108/2014 ([4]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of the authorisation of the preparation of *Clostridium butyricum* FERM BP-2789 as a feed additive for the renewal of the authorisation for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, and for a new authorisation for chickens for fattening, suckling piglets and suckling minor porcine species, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Articles 7(3) and 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2021 ([5]) that the applicant had provided evidence that the additive complies with the conditions of authorisation. The Authority further concluded that the preparation of *Clostridium butyricum* FERM BP-2789 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the preparation is not an irritant to skin

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) No 373/2011 of 15 April 2011 concerning the authorisation of the preparation of *Clostridium butyricum* FERM-BP 2789 as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 903/2009 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium (OJ L 102, 16.4.2011, p. 10).

([3]) Commission Implementing Regulation (EU) No 374/2013 of 23 April 2013 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for chickens reared for laying (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium (OJ L 112, 24.4.2013, p. 13).

([4]) Commission Implementing Regulation (EU) No 1108/2014 of 20 October 2014 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium (OJ L 301, 21.10.2014, p. 16).

([5]) EFSA Journal 2021;19(3):6450.

and eyes and that sensitisation via respiratory route could not be excluded. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards to users of the additive. The Authority also concluded that the additive has the potential to be efficacious in chickens for fattening, suckling piglets and suckling minor porcine species.

(5) The assessment of the preparation of *Clostridium butyricum* FERM BP-2789 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of the preparation of *Clostridium butyricum* FERM BP-2789 as a feed additive under the conditions laid down in the Annex to this Regulation, Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 should be repealed.

(7) 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

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species is renewed, and for the same category and functional group for chickens for fattening, suckling piglets and suckling minor porcine species is authorised subject to the conditions laid down in that Annex.

Article 2

Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 are repealed.

Article 3

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: gut flora stabilisers.									
4b1830	Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium	*Clostridium butyricum* FERM BP-2789	***Additive composition*** Preparation of *Clostridium butyricum* FERM BP-2789 containing a minimum of 5×10^8 CFU/g additive. Solid form ***Characterisation of active substance*** Viable spores of *Clostridium butyricum* FERM BP-2789. ***Analytical method*** (1) Enumeration: pour plate method based on ISO 15213 standard. Identification: pulsed-field gel electrophoresis (PFGE) method	Chickens for fattening Chickens reared for laying Minor avian species (excluding laying birds) Piglets and piglets of minor porcine species	-	$2{,}5 \times 10^8$	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. May be used in feed containing the permitted coccidiostats: decoquinate, diclazuril, lasalocid, maduramicin ammonium, narasin, narasin/nicarbazin, monensin sodium, robenidine, salinomycin sodium and semduramycin sodium. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks 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.	19.9.2031
				Turkeys for fattening Turkeys reared for breeding	-	$1{,}25 \times 10^8$	-		

(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

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1412

of 27 August 2021

concerning the authorisation of Iron(III) citrate chelate as a feed additive for piglets and minor porcine species (holder of the authorisation: Akeso Biomedical, Inc. USA, represented in the Union by Pen & Tec Consulting SLU)

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of ferric citrate chelate. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of ferric citrate chelate as a feed additive for piglets and minor porcine species (suckling and weaned) to be classified in the additive category 'zootechnical additives' and functional group 'other zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 November 2019 ([2]) and 27 January 2021 ([3]) that, under the proposed conditions of use, ferric citrate chelate does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that the additive should be considered a respiratory and skin sensitiser and a potential eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the feed additive has the potential to improve zootechnical parameters of weaned piglets and that this conclusion can be extended to sucking piglets for the period in which solid feed is given and extrapolated to all minor porcine species. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of ferric citrate chelate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised.

(6) In order to align the name of this substance with other, already authorised iron containing additives, 'ferric' should be replaced with the synonym term 'iron(III)'.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019;17(11):5916.
([3]) EFSA Journal 2021;19(3):6455.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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
						mg additive/kg of complete feed with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters).									
4d22	Akeso Biomedical, Inc. USA, represented in the Union by Pen & Tec Consulting SLU	Iron(III) citrate chelate	**Additive composition:** Iron(III) citrate chelate as a powder with a minimum iron(III) content of 15 %, a maximum iron content of 20 %, a maximum nickel content of 50 ppm 5-10 % of a coloured microtracer and a maximum of 10 % moisture. **Characterisation of the active substance:** 2-hydroxy-1,2,3-propanetricarboxylic acid iron(III) Chemical formula: $C_6H_5FeO_7$ CAS number: 3522-50-7. **Analytical method** (1) For the quantification of total iron in the feed additive: — inductively coupled plasma-atomic emission spectrometry, ICP-AES (EN 15510); or	Piglets and minor porcine species (suckling and weaned)	-	550	825	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact, in particular due to the content of heavy metals including nickel. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including skin, eyes and breathing protection. 3. Declaration to be made on the label of the additive and premixture: — content of iron — content of microtracer	19.9.2031

			— inductively coupled plasma-atomic emission spectrometry, ICP-AES with pressure digestion (EN 15621); — atomic absorption spectrometry, AAS (EN ISO 6869); For the quantification of citrate in the feed additive: — ion-exchange high performance liquid chromatography (HPLC) coupled to ultraviolet (UV) detection; For the determination of the added content of iron(III) citrate chelate in premixtures, compound feed and feed materials: — enumeration of colour coated particles of the microtracer present at fixed mass ratio in the feed additive.					4. The amount of iron contained in the additive shall be taken into consideration for the calculation of the total iron content in complete feed.	

(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

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1413

of 27 August 2021

concerning the authorisation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG-S 15136 as a feed additive for lactating sows (holder of the authorisation Beldem, division of Puratos NV)

(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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG-S 15136. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* LMG-S 15136 as a feed additive for lactating sows to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 7 October 2019 ([2]) and 27 January 2021 ([3]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG-S 15136 does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that that additive should be considered a respiratory sensitiser and a potential dermal sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the additive has a potential to be efficacious as a zootechnical additive in sows during the lactation period. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG-S 15136 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) 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

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019;17(11):5892.
([3]) EFSA Journal 2021;19(3):6456.

Article 2

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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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
						Units of activity/kg of complete feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a1606i	Beldem, division of Puratos NV	Endo-1,4-beta-xylanase (EC 3.2.1.8)	Additive composition: Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* LMG-S 15136 having a minimum activity of 400 IU (1)/g. Solid and liquid form. Characterisation of the active substance: Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* LMG-S 15136. Analytical method (2) For the quantification of xylanase activity in the feed additive: — colorimetric method measuring reducing sugars released by action of xylanase on birchwood xylan substrate in the presence of 3,5-dinitrosalicilic acid (DNS). For the quantification of xylanase activity in premixtures, compound feed and feed materials: — colorimetric method measuring water soluble dye released by action of xylanase from azurine cross-linked wheat arabinoxylan substrates.	Lactating sows	-	10 IU	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks 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 eyes, skin and breathing protection.	19.9.2031

(1) 1 IU corresponds to the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4.5 and 30 °C

(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

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1414

of 27 August 2021

correcting Implementing Regulation (EU) 2021/422 concerning the authorisation of a preparation of Enterococcus faecium DSM 7134 as a feed additive for laying hens (holder of authorisation: Lactosan GmbH & Co KG)

(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) The use of the preparation *Enterococcus faecium* DSM 7134 as a feed additive was authorised for laying hens by Commission Implementing Regulation (EU) 2021/422 ([2]) for a 10-year period.

(2) In the Annex to Implementing Regulation (EU) 2021/422, the wrong identification number of the additive has been inserted in the column 'Identification number of the additive'.

(3) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 September 2020 ([3]) that the additive may be used via water for drinking, as part of the conditions of use subject to the safety and efficacy assessment. The specification deriving from that conclusion was not included in the column 'Other provisions' of the Annex to Implementing Regulation (EU) 2021/422, and should therefore be added therein for reasons of legal certainty.

(4) The Authority's opinion also indicated that the additive is not a dermal or ocular irritant, but a potential dermal and respiratory sensitiser. The Annex to Implementing Regulation (EU) 2021/422, in the column 'Other provisions', erroneously refers to the use of breathing protection, glasses and gloves as personal protection equipment, while it should instead refer to the use of breathing and skin protection in order to take appropriate account of the Authority's opinion concerning users' safety.

(5) In the Annex to Implementing Regulation (EU) 2021/422, a minor clerical error has been made as regards the name of the authorisation holder.

(6) Implementing Regulation (EU) 2021/422 should therefore be corrected accordingly. For the sake of clarity, it is appropriate to replace the whole Annex to the said Implementing Regulation by the corrected version thereof.

(7) In order to allow feed business operators to adapt the labelling of the additive and feed containing it to the corrected terms of authorisation, a transitional period should be provided for as regards the placing on the market of those products.

(8) In order to preserve the legitimate expectations of the interested parties in relation to the terms of the authorisation of the additive, this Regulation should enter into force as a matter of urgency.

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

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) 2021/422 of 9 March 2021 concerning the authorisation of a preparation of *Enterococcus faecium* DSM 7134 as a feed additive for laying hens (holder of authorisation: Lactosan GmbH & Co KG) (OJ L 83, 10.3.2021, p. 25).

([3]) EFSA Journal 2020;18(11):6277.

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2021/422 is replaced by the Annex to this Regulation.

Article 2

1. The preparation specified in the Annex and premixtures containing that substance, which are produced and labelled before 1 December 2021 in accordance with the rules applicable before 31 August 2021 may continue to be placed on the market until the existing stocks are exhausted.

2. Feed materials and compound feed containing the preparation and premixtures referred to in paragraph 1 which are produced and labelled before 31 August 2022 in accordance with the rules applicable before 31 August 2021 may continue to be placed on the market until the existing stocks are exhausted.

Article 3

This Regulation shall enter into force on the 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, 27 August 2021.

For the Commission
The President
Ursula VON DER LEYEN

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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			
Category of zootechnical additives. Functional group: gut flora stabilisers											
4b1841	Lactosan GmbH & Co KG	*Enterococcus faecium* DSM 7134	**Additive composition** Preparation of *Enterococcus faecium* DSM 7134 containing a minimum of: Powder: $1x10^{10}$ CFU/g of additive Granules (microencapsulated): $1x10^{10}$ CFU/g of additive **Characterisation of the active substance:** Viable cells of *Enterococcus faecium* DSM 7134 **Analytical method** (1) For enumeration: Spread plate method using bile esculin azid agar (EN 15788). For identification: Pulsed Field Gel Electrophoresis (PFGE).	Laying hens	-	1×10^9	-	5×10^8	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used via water for drinking. 3. For use of the additive in water for drinking the homogenous dispersion of the additive shall be ensured. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or	*30.3.2031*

										reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing and skin protection.'	

([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

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN