EUROPEAN
COMMISSION

Brussels, XXX
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[…](2021) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104 as a feed additive for turkeys for fattening (holder of authorisation: Danisco Animal Nutrition represented by Genencor International B.V.)

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104 as a feed additive for turkeys for fattening (holder of authorisation: Danisco Animal Nutrition represented by Genencor International B.V.)

(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) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104. 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 velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104, previously identified as *Bacillus amyloliquefaciens* PTA-6507, *Bacillus amyloliquefaciens* NRRL B-50013 and *Bacillus amyloliquefaciens* NRRL B-50104 as a feed additive for turkeys for fattening, to be classified in the category ‘zootechnical additives’.

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

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021[2] that under the proposed conditions of use, the preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that this preparation is not irritant to skin and eyes and is not a dermal sensitiser but given the proteinaceous nature of the active agents, the preparation should be 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 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 postmarket 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 velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104 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.

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.

[2] EFSA Journal 2021;19(4):6535.

Done at Brussels,

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									
4b1827i	Danisco Animal Nutrition represented by Genencor International B.V.	*Bacillus velezensis* PTA-6507, *Bacillus. velezensis* NRRL B-50013 and *Bacillus. velezensis* NRRL B-50104	**Additive composition** Preparation of *Bacillus velezensis* PTA-6507, *Bacillus. velezensis* NRRL B-50013 and *Bacillus. velezensis* NRRL B-50104 containing a minimum 2.5 x 10^9 CFU/g additive (total) with a minimum of bacterial concentration of 8.3 x 10^8 of each strain/g additive. Solid form --- **Characterisation of the active substance:** Viable spores of *Bacillus velezensis* PTA-6507, *Bacillus. velezensis* NRRL B-50013 and *Bacillus. velezensis* NRRL B-50104 --- **Analytical method[3]** Identification and enumeration of *Bacillus velezensis* PTA-6507, *Bacillus.*	Turkeys for fattening	-	7.5×10^7	-	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: lasalocid A sodium, monensin sodium and diclazuril**.** 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[3] 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

			velezensis NRRL B-50013 and *Bacillus. velezensis* NRRL B-50104 in the feed additive, premixtures and feedingstuffs - Identification: Pulsed Field Gel Electrophoresis (PFGE) - Enumeration: Spread plate method following heat treatment — EN 15784					measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of disodium 5'-guanylate as a feed additive for all animal species

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of disodium 5'-guanylate 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[4], and in particular Article 9(2) thereof,

Whereas:

(7) 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.

(8) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of disodium 5'-guanylate. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(9) The application concerns the authorisation of disodium 5'-guanylate as a feed additive for all animal species, to be classified in the category 'sensory additives' and in the functional group 'flavouring compounds'.

(10) The applicant requested disodium 5'-guanylate to be authorised also for use in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of disodium 5'-guanylate in water for drinking should not be allowed.

[4] OJ L 268, 18.10.2003, p. 29.

(11) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021[5] that, under the proposed conditions of use, disodium 5'-guanylate does not have adverse effects on animal health, human health or the environment.

(12) The Authority further concluded, that disodium 5'-guanylate is efficacious to contribute to the flavour of feed. The Authority 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.

(13) The assessment of disodium 5'-guanylate 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 as specified in the Annex to this Regulation.

(14) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(15) The fact that disodium 5'-guanylate is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed which is administered via water.

(16) 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 'sensory additives' and to the functional group 'flavouring compounds', 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.

[5] EFSA Journal 2021;19(6):6619.

Done at Brussels,

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 active substance /kg of complete feed with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds									
2b627i	-	Disodium 5'-guanylate	**Additive composition** Disodium 5'-guanylate (GMP). Powder form **Characterisation of the active substance** Disodium 5'-guanylate (hydrated form) produced with *Corynebacterium stationis* KCCM 10530 and *Escherichia coli* K-12 KFCC 11067. Produced by fermentation Purity: min.: 97 % Chemical formula: $C_{10}H_{12}N_5Na_2O_8P$ CAS number: 5550-12-9 EINECS number: 226-914-1	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: "Recommended maximum content of the active substance when used alone or in combination with other ribonucleotides up to the same level per kg of complete feedingstuff with a moisture content of 12%: 50 mg". 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level of active substance in complete feedingstuff referred to in point 3.	[*to be completed by the OP: insert precise date* *10 years from the date of entry into force of this Regulation*]

			Analytical method([6]) For the identification of disodium 5'-guanylate (GMP) in the feed additive: – FAO JECFA monograph "disodium 5'-guanylate" For the determination of disodium 5'-guanylate (GMP) in the feed additive, flavouring premixtures and water: – High performance liquid chromatography coupled to UV detection (HPLC-UV)						

[6] 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

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of the preparation of *Bacillus velezensis* CECT 5940 as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction) (holder of authorisation: Evonik Operations GmbH)

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of the preparation of *Bacillus velezensis* CECT 5940 as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction) (holder of authorisation: Evonik Operations GmbH)

(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[7], and in particular Article 9(2) thereof,

Whereas:

(17) 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 an authorisation.

(18) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of the preparation of *Bacillus velezensis* CECT 5940. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(19) The application concerns the authorisation of the preparation of *Bacillus velezensis* CECT 5940 (previously taxonomically identified as *Bacillus amyloliquefaciens* CECT 5940) as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction), to be classified in the category ‘zootechnical additives’.

[7] OJ L 268, 18.10.2003, p. 29.

(20) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021[8] that, under the proposed conditions of use, the preparation of *Bacillus amyloliquefaciens* CECT 5940 does not have adverse effects on animal health, consumer safety or the environment. It also concluded that this preparation is not an irritant to skin/eye or a skin sensitiser but should be 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 has the potential to be efficacious as a zootechnical additive in feedingstuffs. The Authority does not consider that there is a need for specific requirements of postmarket 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.

(21) The assessment of the preparation of *Bacillus amyloliquefaciens* CECT 5940 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 as specified in the Annex to this Regulation.

(22) 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.

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.

[8] EFSA Journal 2021;19(6):6620.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identi-fication number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi-mum age	Minimum content	Maximum content	Other provisions	End of period of authorisa-tion
						CFU/kg of complete feedingstuff with a moisture content of 12%			
Category of zootechnical additives. Functional group: gut flora stabilisers.									
4b1822i	Evonik Operations GmbH	*Bacillus velezensis* CECT 5940	**Additive composition:** Preparation of *Bacillus velezensis* CECT 5940 containing a minimum of: - 1×10^9 CFU/g additive Solid form --- **Characterisation of the active substance:** Viable spores of *Bacillus velezensis* CECT 5940 --- **Analytical method[9]:** Enumeration: spread plate method using tryptone soya agar (EN 15784);	Turkeys for fattening Turkeys reared for breeding Minor poultry species for fattening and reared for breeding Ornamental birds (except for reproduction)	–	1×10^9	-	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: diclazuril and monensin 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.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[9] 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.

			Identification: pulsed-field gel electrophoresis (PFGE) method.						

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of potassium diformate as a feed additive for pigs for fattening and weaned piglets

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of potassium diformate as a feed additive for pigs for fattening and weaned piglets

(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[10], and in particular Article 9(2) thereof,

Whereas:

(23) 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 an authorisation.

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

(25) The application concerns the authorisation of potassium diformate as a feed additive for pigs for fattening and weaned piglets, to be classified in the category ‘technological additives’.

(26) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 5 May 2021[11] that, under the proposed conditions of use, potassium diformate does not have adverse effects on animal health, consumer safety or the environment. It also concluded that the substance does not raise concerns regarding the effects on the respiratory system and the skin but is an 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.

[10] OJ L 268, 18.10.2003, p. 29.
[11] EFSA Journal 2021;19(5):6617.

The Authority also concluded that the substance has the potential to be efficacious as a technological additive in feedingstuffs. 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.

(27) The assessment of potassium diformate 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 as specified in the Annex to this Regulation.

(28) 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 ‘technological additives’ and to the functional group ‘acidity regulators’, 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,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identi-fication 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 authorisa-tion
					mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: acidity regulators								
1j001	Potassium diformate	**Additive composition:** Potassium diformate ≥ 98% --- **Characterisation of the active substance:** Potassium diformate CAS No: 20642-05-1 EINECS No: 243-934-6 $C_2H_3O_4K$ --- **Analytical method**[12]**:** For the determination of potassium diformate (as total formic acid) in the feed additive, premixture, feedingstuffs: – Ion chromatography with conductivity detection (IC-CD) - EN 17294;	Pigs for fattening Weaned piglets	-	-	6 000	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. The maximum content of potassium diformate shall be 6000 mg/kg of complete feedingstuff with a moisture content of 12%, whether used alone as an acidity regulator or used in combination with other sources of potassium diformate. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks 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	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[12] 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.

Identi-fication 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 authorisa-tion
					mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: acidity regulators								
		For the determination of potassium in the feed additive: – Atomic absorption spectrometry (AAS) - EN ISO 6869; or – Inductively coupled plasma-atomic emission spectrometry (ICP-AES) - EN15510.					personal protective equipment, including eyes protection.	

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366 as a feed additive for all animal species

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366 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[13], and in particular Article 9(2) thereof,

Whereas:

(29) 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 an authorisation.

(30) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-valine. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(31) The application concerns the authorisation of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366 as a feed additive for all animal species, to be classified in the additive category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’.

(32) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 17 March 2021[14] that, under the proposed conditions of use, L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366, when supplemented to diets in appropriate amounts, does not have an adverse effect on animal health, consumer safety or the environment. With respect to the safety of the user of that additive, the Authority could neither exclude a risk by inhalation, nor that L-valine might be irritant to skin or eyes, or a dermal sensitiser. Therefore, the Commission considers that

[13] OJ L 268, 18.10.2003, p. 29.
[14] EFSA Journal 2021;19(4):6521.

appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Further, the Authority concluded that it is considered an efficacious source of the essential amino acid L-valine for animal nutrition and that in order to be efficacious in ruminants, the additive should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(33) The assessment of L-valine produced by *Corynebacterium glutamicum* CGMCC 7.366 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.

(34) 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 ‘amino acids, their salts and analogues’, is authorised as a feed 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,

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/kg of complete feed with a moisture content of 12%			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c371ii	-	L-valine	**Additive composition:** Powder with a minimum content of L-valine of 98 % (on a dry matter basis) and a maximum content of 1,5% water. --- **Characterisation of the active substance :** L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by *Corynebacterium glutamicum* CGMCC 7.366 Chemical formula: $C_5H_{11}NO_2$ CAS number: 72-18-4 --- **Analytical method[15]:** For the identification of L-valine in the feed additive: - Food Chemical Codex "L-valine monograph" For the quantification of valine in the feed additive: - ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) For the quantification of valine in premixtures, feed materials and compound feed: - ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) –	All species	-			1.The additive may be used via water for drinking. 2. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 3.The label of the additive and premixture shall indicate the following: 'The supplementation with L-valine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 4. For users of the additive and	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

15 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 Regulation (EC) No 152/2009 (Annex III, F) For the quantification of valine in water: - ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FD)					premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal 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 appropriate personal protective equipment, including eyes, skin and breathing protection.	

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-lysine base, L-lysine monohydrochloride and L-lysine sulphate as feed additives for all animal species

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-lysine base, L-lysine monohydrochloride and L-lysine sulphate 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[16], and in particular Article 9(2) thereof,

Whereas:

(35) 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 an authorisation.

(36) In accordance with Article 7 of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of L-lysine base, L-lysine monohydrochloride and L-lysine sulphate. The applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(37) The applications concern the authorisation of L-lysine base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 as feed additives for all animal species, to be classified in the additive category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’.

[16] OJ L 268, 18.10.2003, p. 29.

(38) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 March 2021[17,18] and 23 June 2021[19] that, under the proposed conditions of use, L-lysine base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 do not have an adverse effect on animal health, consumer safety or the environment. For L-lysine sulfate produced by *Corynebacterium glutamicum* KCCM 80227, the Authority concluded that that active substance is not toxic by inhalation, not irritant to skin or eyes, and not a skin sensitiser. With respect to the safety of the user of L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595, the Authority could neither exclude a risk by inhalation, nor that the active substance might be irritant to skin or eyes, or a dermal sensitiser. Further, the Authority stated L-lysine base produced by *Corynebacterium glutamicum* KCCM 80183 to be hazardous by inhalation and L-Lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183 to be hazardous by inhalation and mildly irritant to eyes. Therefore, the Commission considers that for the lysine forms produced by *Corynebacterium glutamicum* CCTCC M 2015595 and *Corynebacterium glutamicum* KCCM 80183, 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 all additives are efficacious sources of the amino acid L-lysine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the additives should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(39) The assessments of L-lysine base and L-lysine monohydrochloride produced by *Corynebacterium glutamicum* KCCM 80183, L-lysine monohydrochloride and L-lysine sulphate produced by *Corynebacterium glutamicum* CCTCC M 2015595 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 80227 show that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

(40) 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 substances and preparations specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', are authorised as additives in animal nutrition subject to the conditions laid down in that Annex.

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17 EFSA Journal 2021;19(4):6520.
18 EFSA Journal 2021;19(4):6537.
19 EFSA Journal 2021;19(7):6706.

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,

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 nutritional additives. Functional group: amino acids, their salts and analogues.									
3c320	-	L-lysine base, liquid	**Additive composition:** Preparation (aqueous solution) of L-lysine with a minimum of 50 % L-lysine. --- **Characterisation of the active substance:** L-lysine produced by fermentation with *Corynebacterium glutamicum* KCCM 80183 Chemical formula: NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH CAS Number: 56-87-1 --- **Analytical methods[20]:** For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: − ion exchange chromatography coupled with post-column derivatisation and	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive can be also used via water for drinking. 3. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

[20] 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

			optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS).					take into account all essential and conditional essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal 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 appropriate personal protective equipment, including eyes, skin and breathing protection.	

3c322ii		L-lysine monohydrochloride, technically pure	**Additive composition:** Powder of L-lysine monohydrochloride with a minimum of 78% L-lysine and a maximum moisture content of 1,5%. **Characterisation of the active substance:** L-lysine monohydrochloride produced by fermentation with *Corynebacterium glutamicum* KCCM 80183 or *Corynebacterium glutamicum* CCTCC M 2015595 Chemical formula: NH_2-$(CH_2)_4$-$CH(NH_2)$-COOH CAS Number: 657-27-2 **Analytical methods[21]:** For the identification of L-lysine monohydrochloride in the feed additive: − Food Chemical Codex "L-lysine monohydrochloride monograph" For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water:	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. The additive can be also used via water for drinking. 4. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation, eye or dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

[21] 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

			− ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or − ion exchange chromatography coupled with post-column derivatisation and opticaloptical detection (IEC-VIS).					measures, the additive and premixtures shall be used with appropriate personal protective equipment, including eyes, skin and breathing protection.	
3c325i	-	L-lysine sulphate	**Additive composition:** Granulated preparation of L-lysine sulphate with a minimum L-lysine content of 52%, a maximum content of 24% sulphate and a maximum content of 4% moisture. **Characterisation of the active substance:** L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* CCTCCM 2015595 Chemical formula: C_{12} H_{28} N_4O_4•H_2SO_4/ $[NH_2$-$(C$ $H_2)_4$-$CH(NH_2)$-$COOH]_2SO_4$ CAS number: 60343-69-3 **Analytical methods[22]:**	All species	-	-	10 000	1.The L-lysine content shall be indicated on the labelling of the additive. 2. The additive may be also used via water for drinking. 3. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

[22] 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

			For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: − ion exchange chromatography coupled with post-column derivatisation and opticaloptical detection (IEC-VIS/FLD) – EN ISO 17180 For the identification of sulphate in the feed additive: − European Pharmacopoeia Monograph 20301 For the quantification of lysine in premixtures, compound feed and feed materials: − ion exchange chromatography coupled with post-column derivatisation and opticaloptical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of lysine in water: − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)					for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum level by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	
3c324i	-	L-lysine sulphate	**Additive composition:** Granulated preparation of L-lysine sulphate with a minimum L-lysine content of 52 %, a maximum content of 24 % sulphate and a maximum content of 4% moisture. **Characterisation of the active substance:**	All species	-	-		1. The L-lysine content shall be indicated on the labelling of the additive. 2. Declarations to be made on the labelling of the additive and premixtures: 'The	*[10 years from the date of entry into force of this Regulation. To be completed by the Service*

			L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* KCCM 80227 Chemical formula: C_{12} H_{28} N_4O_4•H_2SO_4/ $[NH_2$-$(C$ $H_2)_4$-$CH(NH_2)$-$COOH]_2SO_4$ CAS number: 60343-69-3 **Analytical methods[23]:** For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: − ion exchange chromatography coupled with post-column derivatisation and opticaloptical detection (IEC-VIS/FLD) – EN ISO 17180 For the identification of sulphate in the feed additive: − European Pharmacopoeia Monograph 20301 For the quantification of lysine in premixtures, compound feed and feed materials: − ion exchange chromatography coupled with post-column derivatisation and opticaloptical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of lysine in water: − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)					supplementation with L-lysine should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	*responsible for the publication]*

[23] 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

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species (holder of the authorisation: Danisco (UK) Ltd, represented in the Union by Genencor International B.V.)

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species (holder of the authorisation: Danisco (UK) Ltd, represented in the Union by Genencor International B.V.)

(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[24], and in particular Article 9(2) thereof,

Whereas:

(41) 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 an authorisation.

(42) 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 *Trichoderma reesei* CBS 143953. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(43) That application concerns the authorisation of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’.

[24] OJ L 268, 18.10.2003, p. 29.

(44) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021[25] that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species 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 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 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.

(45) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 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.

(46) 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.

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.

[25] EFSA Journal 2021;19(5):6539.

Done at Brussels,

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 Units of activity/kg of complete feed with a moisture content of 12%		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a11	Danisco (UK) Ltd, represented in the Union by Genencor International B.V.	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 *Trichoderma reesei* CBS 143953 with a minimum activity of 40 000 U/g[26] --- ***Characterisation of active substance*** Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* CBS 143953 --- ***Analytical method[27]*** For quantification of endo-1,4-beta-xylanase activity: colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrates	All poultry species Pigs for fattening Piglets (weaned and suckling) All minor porcine species	–	625 U 2 000 U	-	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 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 eyes and breathing protection.	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

[26] 1 U is the amount of enzyme which releases 0,48 µmol of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH 4,2 and 50 °C.

[27] 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

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Brussels, XXX
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[…](2021) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive for all animal species except finfish

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive for all animal species except finfish

(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[28], and in particular Article 9(2) thereof,

Whereas:

(47) 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 an authorisation.

(48) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the extension of use of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive from finfish to all animal species. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(49) The application concerns the authorisation of the extension of use of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 as a feed additive from finfish to all animal species to be classified in the additive category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’, and in the additive category ‘sensory additives’, functional group ‘flavouring compounds’.

[28] OJ L 268, 18.10.2003, p. 29.

(50) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 May 2021[29] that, under the proposed conditions of use, L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia co*li NITE SD 00268 does not have an adverse effect on animal health, consumers safety or the environment. The Authority also concluded for the additive in question that it was not possible to conclude on the potential for the additive to be toxic if inhaled, an irritant to eyes or a skin 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 additive is an efficacious source of the essential amino acid histidine and efficacious as a flavouring compound.

(51) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(52) The assessment of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive should be authorised as specified in the Annex to this Regulation.

(53) 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

1. The substance L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

2. The substance L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds' is authorised as a feed 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*.

[29] EFSA Journal 2021; 19(5):6622.

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

Done at Brussels,

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/kg of complete feed with a moisture content of 12%			
Category: nutritional additives. Functional group: amino acids, their salts and analogues.									
3c351i	-	L-histidine monohydrochloride monohydrate	**Additive composition:** Powder with a minimum content of 98 % L-histidine monohydrochloride monohydrate and 72 % histidine and a maximum content of 100 ppm histamine --- **Characterisation of the active substance:** L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268 Chemical formula: $C_3H_3N_2$-CH_2-CH(NH_2)-COOH·HCl·H_2O CAS number: 5934-29-2 EINECS number 211-438-9 --- **Analytical method[30]:** For the quantification of histidine in the feed additive: − high performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV); − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD);	All animal species except finfish	-	-	-	1. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 2. Declaration to be made on the label of the additive and premixture: − 'The supplementation with L-histidine monohydrochloride monohydrate shall be limited to the nutritional requirements of the target animal, which depend on the species, the physiological state of the animal, the performance level, the environmental conditions, the level of other amino acids in the diet and the level of essential trace elements, such as copper and zinc.' − 'Histidine content'.	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*

30 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

			For the quantification of histidine in premixtures, feed materials and compound feed: – ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F); For the quantification of histamine in the feed additive: – high performance liquid chromatography coupled to a spectrophotometric detection (HPLC-UV)					3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal 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 appropriate personal protective equipment, including eyes, skin and breathing protection.	
Category: Sensory additives. Functional group: Flavouring compounds									
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 of active substance/kg of complete feed with a moisture content of 12%			
3c351i	-	L-histidine monohydrochloride monohydrate	**Additive composition:** Powder with a minimum content of 98 % L-histidine monohydrochloride monohydrate and 72 % histidine and a maximum content of 100 ppm histamine --- **Characterisation of the active substance:** L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE SD 00268	All animal species	–	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the*

			Chemical formula: $C_3H_3N_2$-CH_2-CH(NH_2)-COOH·HCl·H_2O CAS number: 5934-29-2 EINECS number 211-438-9 ---------- **Analytical method[31]:** For the quantification of histidine in the feed additive: − high performance liquid chromatography coupled with spectrophotometric detection (HPLC-UV); − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); For the quantification of histidine in premixtures: − ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F); For the quantification of histamine in the feed additive: − high performance liquid chromatography coupled to a spectrophotometric detection (HPLC-UV)					maximum content of the active substance of complete feed with a moisture content of 12 %: 25 mg/kg. 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture, where the use level on the label of the premixture would result in exceeding the level of active substance in complete feed referred to in point 3. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks by inhalation or dermal 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 appropriate personal protective equipment, including eyes, skin and breathing protection.	*publicatio n]*

[31] 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

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Brussels, XXX
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[…](2021) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of the authorisation Novus Europe NV)

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of the authorisation Novus Europe 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[32], and in particular Article 9(2) thereof,

Whereas:

(54) 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.

(55) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(56) The application concerns the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for turkeys for fattening and turkeys reared for breeding, to be classified in the additive category `zootechnical additives', functional group `other zootechnical additives´.

[32] OJ L 268, 18.10.2003, p. 29.

(57) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021[33] that, under the proposed conditions of use, the preparation of benzoic acid, calcium formate and fumaric acid does not have an adverse effect on animal health, consumer safety or the environment. The Authority concluded that the additive presents a low inhalation risk for its users. 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 additive has the potential to improve the performance of turkeys for fattening and this conclusion can be extended to turkeys reared for breeding. 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.

(58) The assessment of the preparation of benzoic acid, calcium formate and fumaric acid 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.

(59) 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 '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.

[33] EFSA Journal 2021;19(4):6528.

Done at Brussels,

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 of additive/kg of complete feed with a moisture content of 12%			
Category of zootechnical additives. Functional group: other zootechnical additives (improving zootechnical performance).									
4d14	Novus Europe NV	Preparation of benzoic acid, calcium formate and fumaric acid	**Additive composition:** Preparation of benzoic acid, calcium formate and fumaric acid having a minimum content of: benzoic acid: 42.5-50 %, calcium formate: 2.5-3.5 %, fumaric acid: 0.8-1.2 %; Granulated form --- **Characterisation of the active substance:** Benzoic acid (purity ≥99,0%); CAS number: 65-85-0; Chemical formula $C_7H_6O_2$ Calcium formate: CAS number 544-17-2; Chemical formula $C_2H_2O_4Ca$;	Turkeys for fattening Turkeys reared for breeding	-	500	1000	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 shall not be used with other sources of benzoic acid or benzoates, calcium formate or formic acid and fumaric acid. 3. For users of the additive and premixtures, feed business operators	*[10 years from the date of entry into force of this Regulation.* *To be completed by the Service responsible for the publication]*

			Fumaric acid (purity ≥99,5%): CAS number 110-17-8; Chemical formula $C_4H_4O_4$. --- **Analytical method**[34] For the determination of benzoic acid, calcium formate and fumaric acid in the feed additive: - high performance liquid chromatography with UV detection (HPLC-UV); For the determination of total calcium in the feed additive: - atomic absorption spectrometry (AAS) – EN ISO 6869; or - inductively coupled plasma atomic emission spectrometry (ICP-AES) – EN 15510; For the determination of benzoic acid in premixtures and feedingstuffs: - high performance liquid chromatography with UV detection (HPLC-UV); For the determination of calcium formate and fumaric acid in premixtures: - ion-exclusion high performance liquid chromatography with UV or refractive index detection (HPLC-UV/RI).					shall establish operational procedures and organisational measures to address potential risks concerning 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.	

[34] 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.

EUROPEAN
COMMISSION

Brussels, XXX
SANTE /10858/2021 CIS
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CIS.docx)
[…](2021) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the denial of authorisation of titanium dioxide as a feed additive for all animal species

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the denial of authorisation of titanium dioxide 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[35], and in particular Article 9(2) thereof,

Whereas:

(60) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[36].

(61) Titanium dioxide was authorised without a time limit by Directive 70/524/EEC as a colourant additive (colouring agents authorised for colouring foodstuffs by Community rules) for cats and dogs. It was also authorised without a time limit for all animal species, with the exception of cats and dogs, for animal feedingstuffs under certain conditions. That product 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.

(62) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of titanium dioxide as a feed additive for all animal species. The applicant requested the additive to be classified in the additive

35 OJ L 268, 18.10.2003, p. 29.

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

category ‘sensory additives’ and the functional group ‘colourants: substances that add or restore colour in feedingstuffs’. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(63) The European Food Safety Authority (‘the Authority’) noted in its opinion of 5 May 2021[37] that it could not conclude on the safety of titanium dioxide for the target species, consumers and environment, given the absence of specific data related to its use as a feed additive and considering that the genotoxicity of particles of titanium dioxide could not be ruled out, raising potential concerns on the safety of the additive for the target species (especially for long-living animals and reproductive animals), consumers and users. In the absence of studies with titanium dioxide, the Authority could not conclude on the assessment of the effects of the additive on eyes and skin. The Authority further noted that titanium dioxide is potentially carcinogenic to workers if inhaled and that, as the genotoxicity of particles of titanium dioxide cannot be ruled out, it should be considered as an additional potential concern to users handling the additive. The Authority 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.

(64) The Authority’s opinion of 5 May 2021 shows, therefore, that it has not been established that titanium dioxide does not have an adverse effect on animal health, human health or the environment, when used as a feed additive in the functional group ‘colourants: substances that add or restore colour in feedingstuffs’.

(65) The assessment of titanium dioxide thus shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied and accordingly, the authorisation of titanium dioxide as a feed additive belonging to the functional group ‘colourants: substances that add or restore colour in feedingstuffs’ should be denied.

(66) Therefore, the feed additive titanium dioxide and feed containing it should be withdrawn from the market as soon as possible. However, a limited period should be allowed for the withdrawal from the market of the existing stocks of those products, in order to enable operators to comply properly with the withdrawal obligation.

(67) 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

Denial of authorisation

The authorisation of titanium dioxide (E 171) as an additive in animal nutrition, in the additive category ‘sensory additives’ and in the functional group ‘colourants: substances that add or restore colour in feedingstuffs’, is denied.

[37] EFSA Journal 2021;19(6):6630.

Article 2

Withdrawal from the market

1. Existing stocks of the additive referred to in Article 1 and of premixtures containing it, shall be withdrawn from the market by *[OP please insert the date = 3 months after the date of entry into force of this Regulation]*.

2. Feed materials and compound feed which have been produced with the additive or the premixtures referred to in paragraph 1 before [*OP please insert the date = 3 months after the date of entry into force of this Regulation*] shall be withdrawn from the market by [*OP please insert the date = 6 months after the date of entry into force of this Regulation*].

Article 3

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,

For the Commission
The President
Ursula VON DER LEYEN