

Official Journal

of the European Union

L 2



English edition

Legislation

Volume 62

4 January 2019

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2019/7 of 30 October 2018 amending Regulation (EU) No 1031/2010 as regards the auctioning of 50 million unallocated allowances from the market stability reserve for the innovation fund and to list an auction platform to be appointed by Germany ⁽¹⁾** 1
- ★ **Commission Implementing Regulation (EU) 2019/8 of 3 January 2019 concerning the authorisation of hydroxy analogue of methionine and its calcium salt as a feed additive for all animal species ⁽¹⁾** 6
- ★ **Commission Implementing Regulation (EU) 2019/9 of 3 January 2019 concerning the authorisation of betaine anhydrous as a feed additive for food-producing animals except rabbits ⁽¹⁾** 10
- ★ **Commission Implementing Regulation (EU) 2019/10 of 3 January 2019 concerning the authorisation of a preparation of a natural mixture of illite- montmorillonite-kaolinite as a feed additive for all animal species ⁽¹⁾** 13
- ★ **Commission Implementing Regulation (EU) 2019/11 of 3 January 2019 concerning the authorisation of the preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for sows, suckling piglets, weaned piglets, pigs for fattening, and amending Regulations (EC) No 252/2006, (EC) No 943/2005 and (EC) No 1200/2005 (holder of authorisation DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. z o.o.) ⁽¹⁾** 17
- ★ **Commission Implementing Regulation (EU) 2019/12 of 3 January 2019 concerning the authorisation of L-arginine as a feed additive for all animal species ⁽¹⁾** 21

Corrigenda

- ★ **Corrigendum to Regulation (EU) 2018/231 of the European Central Bank of 26 January 2018 on statistical reporting requirements for pension funds (ECB/2018/2) (OJ L 45, 17.2.2018)** 27

⁽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.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2019/7

of 30 October 2018

amending Regulation (EU) No 1031/2010 as regards the auctioning of 50 million unallocated allowances from the market stability reserve for the innovation fund and to list an auction platform to be appointed by Germany

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2003/87/EC of the European Parliament and of the Council of 13 October 2003 establishing a system for greenhouse gas emission allowance trading within the Union and amending Council Directive 96/61/EC ⁽¹⁾, and in particular Articles 3d(3), 10(4) and 10a(8) thereof,

Whereas:

- (1) Directive 2003/87/EC establishes a fund to provide financial support to innovation in low-carbon technologies within the territory of the Union by making 400 million allowances available from the total volume of allowances for the period 2021 to 2030 as part of the EU Emission Trading System ('innovation fund'). In addition, 50 million unallocated allowances from the market stability reserve should supplement any remaining revenues from the 300 million allowances available in the period from 2013 to 2020 under Commission Decision 2010/670/EU ⁽²⁾, and should be used in a timely manner for the innovation fund before 2021.
- (2) In order to ensure that the innovation fund is in a position to provide support before 2021, it is necessary to monetise the 50 million allowances for the innovation fund by means of auctions in accordance with the rules and modalities for auctions on the Common Auction Platform, which are established by Commission Regulation (EU) No 1031/2010 ⁽³⁾.
- (3) With the aim to reduce the administrative burden on Member States and to improve overall efficiency, the volume of 50 million allowances for the innovation fund should be added to the volumes of allowances to be auctioned at the Common Auction Platform in 2020 by the Member States that as at 1 January 2018 were participating in the joint action pursuant to Article 26 of Commission Regulation (EU) No 1031/2010.
- (4) The participating Member States should auction their share of the 50 million allowances for the innovation fund through their auctioneers. In order to receive the respective innovation fund proceeds, each auctioneer should designate, by 1 October 2019, an auctioneer's nominated bank account for the receipt of these auction proceeds. The auctioneers may designate their existing auctioneer's nominated bank account for the auction

⁽¹⁾ OJ L 275, 25.10.2003, p. 32.

⁽²⁾ Commission Decision 2010/670/EU of 3 November 2010 laying down criteria and measures for the financing of commercial demonstration projects that aim at the environmentally safe capture and geological storage of CO₂ as well as demonstration projects of innovative renewable energy technologies under the system for greenhouse gas emission allowance trading within the Union established by Directive 2003/87/EC of the European Parliament and of the Council (OJ L 290, 6.11.2010, p. 39).

⁽³⁾ Commission Regulation (EU) No 1031/2010 of 12 November 2010 on the timing, administration and other aspects of auctioning of greenhouse gas emission allowances pursuant to Directive 2003/87/EC of the European Parliament and of the Council establishing a scheme for greenhouse gas emission allowances trading within the Community (OJ L 302, 18.11.2010, p. 1).

proceeds due to their Member State, a separate auctioneer's nominated bank account dedicated for the auction proceeds of the innovation fund, or the auctioneer's nominated bank account of another auctioneer of a Member State that will auction allowances for the innovation fund.

- (5) The auctioneers appointed to conduct the auctioning of the 50 million allowances for the innovation fund should ensure that the auction proceeds for the innovation fund are disbursed in the account notified to them by the Commission for the purposes of that fund, at the latest 15 days following the end of the month within which the auction proceeds were generated.
- (6) Any additional fees resulting from the holding of these auction proceeds in the auctioneer's nominated bank account and from their disbursement may be deducted by the auctioneer from the auction proceeds prior to their disbursement. Before the first deduction and before any change to such fees, the respective auctioneer's Member State should notify to the Commission and all other Member States the amount and the purpose of the additional fees its auctioneer intends to deduct.
- (7) Article 61 of Regulation (EU) No 1031/2010 currently provides for the simultaneous announcement by the auction platform of the detailed results of each auction and the notification to the successful bidders of the individual results. However, the level of detail of the auction results to be announced does not allow for their publication simultaneously with the notification of the individual results to the successful bidders. In order to align this provision with market practice and to safeguard against market abuse, the auction platform may publish, prior to the announcement of the remaining auction result details, the volume of allowances auctioned and the auction clearing price, so that these are published simultaneously as the platform notifies the individual results of the auction to the successful bidders. The remaining auction results should be announced no later than 15 minutes after the closure of the bidding window.
- (8) Regulation (EU) No 1031/2010 allows Member States not participating in the joint action as provided in paragraphs 1 and 2 of Article 26 of that Regulation to appoint their own auction platform for the auctioning of their share of the volume of allowances covered by Chapters II and III of Directive 2003/87/EC. The appointment of such auction platforms is subject to listing of the auction platform concerned in Annex III, in accordance with the third subparagraph of Article 30(5) of Regulation (EU) No 1031/2010.
- (9) In accordance with Article 30(4) of Regulation (EU) No 1031/2010, Germany informed the Commission of its decision not to participate in the joint action as provided in paragraphs 1 and 2 of Article 26 of that Regulation, and to appoint its own auction platform.
- (10) On 12 April 2018, Germany notified the Commission its intention to appoint European Energy Exchange AG as an auction platform referred to in Article 30(1) of Regulation (EU) No 1031/2010 for a maximum period of five years from the entry into force of this Regulation. The term of appointment, the legal basis for the appointment and the applicable conditions and obligations for European Energy Exchange AG as the auction platform for Germany for that period should be listed in the Annex III to Regulation (EU) No 1031/2010.
- (11) Regulation (EU) No 1031/2010 should therefore be amended accordingly.
- (12) In order to ensure predictable and timely auctions by the auction platform to be appointed by Germany, this Regulation should enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1031/2010 is amended as follows:

- (1) In Article 10, the following paragraph 5 is added:

'5. The volume of allowances covered by Chapter III of Directive 2003/87/EC to be auctioned in 2020 shall also include the volume of 50 million unallocated allowances from the market stability reserve referred to in the second subparagraph of Article 10a(8) of that Directive. Those allowances shall be divided in equal amounts between the Member States participating in the joint action pursuant to Article 26(1) of this Regulation as at 1 January 2018 and shall be added to the volume of allowances to be auctioned for each of them. The volume of 50 million allowances shall in principle be distributed evenly over the auctions held in 2020.'

(2) Article 23 is replaced by the following:

'Article 23

The auctioneer's functions

1. The auctioneer shall carry out the following functions:

- (a) auction the volume of allowances to be auctioned by each Member State appointing it;
- (b) receive the auction proceeds due to each Member State appointing it;
- (c) disburse the auction proceeds due to each Member State appointing it.

2. The auctioneer of each Member State auctioning allowances pursuant to Article 10(5) shall receive the auction proceeds from those allowances on an auctioneer's nominated bank account designated by it no later than 1 October 2019 for the receipt of payments due under Article 10(5). The auctioneer shall ensure that these auction proceeds are disbursed to the account notified to it by the Commission for the purposes of Article 10a(8) of Directive 2003/87/EC, at the latest 15 days following the end of the month within which the auction proceeds were generated. The auctioneer may deduct prior to disbursement any additional fees for their holding and disbursement, subject to the prior notification of the amount and the reason for these fees by its Member State to the Commission and all other Member States.'

(3) Paragraph 2 of Article 61 is replaced by the following:

'2. Pursuant to paragraph 1 the auction platform shall announce at least the following results of each auction:

- (a) the volume of the allowances auctioned;
- (b) the auction clearing price in euros;
- (c) the total volume of bids submitted;
- (d) the total number of bidders and the number of successful bidders;
- (e) in case of cancellation of an auction, the auctions to which the volume of allowances will be carried over;
- (f) the total revenue earned from the auction;
- (g) the distribution of the revenue between the Member States, in the case of auction platforms appointed pursuant to Article 26(1) or (2).'

(4) Paragraph 3 of Article 61 is replaced by the following:

'3. At the same time as the auction platform announces the results of each auction pursuant to points (a) and (b) of paragraph 2, the auction platform shall notify each successful bidder bidding through its systems:

- (a) the total number of allowances to be allocated to that bidder;
- (b) which of its tied bids, if any, were randomly selected;
- (c) the payment due either in euros or in the currency of a Member State not member of the euro-zone, chosen by the bidder provided that the clearing system or settlement system is capable of handling the national currency in question;
- (d) the date by which the payment due must be paid in cleared funds into the auctioneer's nominated bank account.'

(5) Annex III is amended in accordance with the Annex to this Regulation.

Article 2

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, 30 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex III to Regulation (EU) No 1031/2010, the following part 5 is added:

'Auction platforms appointed by Germany		
5	Auction platform	European Energy Exchange AG (EEX)
	Legal Basis	Article 30(1)
	Term of appointment	From 5 January 2019 at the earliest for a maximum period of five years until 4 January 2024, without prejudice to the second subparagraph of Article 30(5).
	Conditions	Admission to the auctions shall not be dependent on becoming a member of or a participant in the secondary market organised by EEX or of any other trading place operated by EEX or by any third party.
	Obligations	<ol style="list-style-type: none">1. Within two months from 5 January 2019, EEX shall submit its exit strategy to Germany. The exit strategy shall be without prejudice to the obligations of EEX laid down in the contract with the Commission and the Member States concluded pursuant to Article 26 and the rights of the Commission and those Member States under that contract.2. Germany shall notify the Commission of any substantive changes in the relevant contractual relations with EEX notified to the Commission on 12 April 2018.'

COMMISSION IMPLEMENTING REGULATION (EU) 2019/8**of 3 January 2019****concerning the authorisation of hydroxy analogue of methionine and its calcium salt as a feed additive for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of hydroxy analogue of methionine and its calcium salt as a feed additive for use in feed for all animal species. 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 hydroxy analogue of methionine and its calcium salt as a feed additive for all animal species to be classified in the additive category 'nutritional additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 February 2018 ⁽²⁾ that, under the proposed conditions of use, hydroxy analogue of methionine and its calcium salt does not have an adverse effect on animal health, human health or the environment.
- (5) The Authority also concluded that the additive is an effective source of methionine for all animal species and that, even though the ruminal degradation of the additive in ruminants is lower than that of DL-methionine, the additive should be protected against degradation in the rumen.
- (6) 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.
- (7) The assessment of this additive 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.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1***Authorisation**

The substance specified in the Annex, belonging to the additive category '*nutritional additives*' and to the functional group '*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***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*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2018;16(3):5198.

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

Done at Brussels, 3 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c310	—	Hydroxy analogue of methionine and its calcium salt	<p><i>Additive composition:</i></p> <p>Preparation of hydroxy analogue of methionine and calcium salt of hydroxy analogue of methionine, having a minimum content of hydroxy analogue of methionine of 88 % and a minimum content of calcium of 8 %.</p> <p><i>Characterisation of the active substances:</i></p> <p>Hydroxy analogue of methionine:</p> <p>IUPAC name: 2-hydroxy-4-(methylthio)butanoic acid</p> <p>CAS number 583-91-5</p> <p>Chemical formula: $C_5H_{10}O_3S$</p> <p>calcium salt of hydroxy analogue of methionine:</p> <p>IUPAC name 2-hydroxy-4-(methylthio)butanoic acid, calcium salt</p> <p>CAS number 4857-44-7</p> <p>Chemical formula: $(C_5H_9O_3S)_2Ca$</p> <p><i>Analytical method ⁽¹⁾:</i></p> <p>For the determination of hydroxy analogue of methionine in the additive:</p> <p>— Titrimetry, potentiometric titration after oxidation reduction reaction.</p>	All animal species	—	—	—	<ol style="list-style-type: none"> 1. 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, in particular considering that it is corrosive to skin and eyes. 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 safety glasses and gloves. 2. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 3. Declaration to be made on the label of the additive and premixture: content of hydroxy analogue of methionine. 	24 January 2029

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 %			
			<p>For the determination of hydroxy analogue of methionine in premixtures, compound feed and feed materials:</p> <ul style="list-style-type: none"> — High-Performance Liquid Chromatography and photometric detection (HPLC-UV). <p>For the determination of total calcium in the additive:</p> <ul style="list-style-type: none"> — Atomic Absorption Spectrometry, AAS (EN ISO 6869); or — Inductively Coupled Plasma – Atomic Emission Spectrometry, ICP-AES (EN 15510); or — Inductively Coupled Plasma – Atomic Emission Spectrometry after pressure digestion, ICP-AES (EN 15621). 					<p>4. The labelling of feed materials and compound feed, into which the additive has been incorporated, shall contain in the listing of additives information as regards:</p> <ul style="list-style-type: none"> — Name of the additive, — Amount of the hydroxy analogue of methionine added. 	

(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) 2019/9
of 3 January 2019
concerning the authorisation of betaine anhydrous as a feed additive for food-producing animals
except rabbits

(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 betaine anhydrous. That 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 betaine anhydrous as a feed additive for food-producing animals to be classified in the additive functional group 'vitamins, provitamins and chemically well-defined substances having a similar effect'. Subsequently, the applicant withdrew the application for rabbits.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 June 2018 ⁽²⁾ that, under the proposed conditions of use, betaine anhydrous does not have adverse effects on animal health, human health or the environment. The Authority concluded that betaine anhydrous has a nutritional role and is an effective source of betaine with a potential to be efficacious in all animal species.
- (5) The Authority further noted that the solid form has the potential to generate dust; therefore, exposure by inhalation cannot be excluded. In addition, the Authority stated that betaine anhydrous should be considered hazardous by inhalation, irritant to skin, eyes and mucous membranes and a skin sensitiser. Consequently, appropriate protective measures should be taken with respect to the handling of the solid form of betaine anhydrous.
- (6) The Authority concluded that the liquid form of betaine anhydrous contains a high proportion of unknown material; therefore, it is not possible to conclude on its safety. Consequently, only the solid form should be authorised.
- (7) 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.
- (8) The assessment of betaine anhydrous 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.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, provitamins and chemically well-defined substances having 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⁾ EFSA Journal 2018;16(7):5335

*Article 2***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, 3 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			

Category of nutritional additives. Functional group: vitamins, provitamins and chemically well-defined substances having a similar effect

3a921i	AB Vista Iberia S.L.	Betaine anhydrous produced from genetically modified sugar beet	<p><i>Additive composition</i></p> <p>Betaine anhydrous</p> <p><i>Characterisation of the active substance</i></p> <p>Betaine C₅H₁₁NO₂</p> <p>CAS number: 107-43-7</p> <p>Betaine anhydrous, crystalline solid form, produced by extraction from genetically modified KM-ØØØH71-4 sugar beet.</p> <p>Purity criteria: min. 97 % (on anhydrous basis)</p> <p><i>Method of Analysis</i> ⁽¹⁾</p> <p>For the determination of betaine anhydrous (expressed as total betaine) in the <i>feed additive, premixtures, and feedingstuffs</i>. High Performance Liquid Chromatography method with refractive index detector (HPLC-RI).</p>	Food-producing animals except rabbits	—	—		<ol style="list-style-type: none"> Betaine anhydrous may be placed on the market and used as an additive consisting of a preparation. In the directions for use of the additive and premixtures, the storage and stability to heat treatment shall be indicated. On the label of the additive and the premixture the following shall be indicated 'Recommended not to exceed levels of: 2 000 mg of betaine/kg of complete feed (with a moisture content of 12 %)'. 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 breathing protection, safety glasses and gloves. 	4 August 2028
--------	----------------------	---	---	---------------------------------------	---	---	--	---	---------------

⁽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) 2019/10**of 3 January 2019****concerning the authorisation of a preparation of a natural mixture of illite- montmorillonite-kaolinite as a feed additive for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of a natural mixture of illite-montmorillonite-kaolinite. That 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 a preparation of a natural mixture of illite-montmorillonite-kaolinite as a feed additive for all animal species, to be classified in the additive category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 1 December 2015 ⁽²⁾, 5 July 2017 ⁽³⁾ and 5 July 2018 ⁽⁴⁾ that, under the proposed conditions of use, the preparation of a natural mixture of illite-montmorillonite-kaolinite does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that it is effective as a binder and anticaking agent. 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 a natural mixture of illite-montmorillonite-kaolinite 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 'technological additives' and to the functional group 'binders' and 'anticaking agents', is authorised as an additive in animal nutrition, subject to the conditions laid down in the 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*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2016; 14(1):4342.

⁽³⁾ EFSA Journal 2017; 15(7):4940.

⁽⁴⁾ EFSA Journal 2018; 16(7):5387.

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

Done at Brussels, 3 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Technological additives: binders								
1g599	Illite-montmorillonite-kaolinite	<p><i>Additive composition</i></p> <p>Preparation of a natural mixture of illite- montmorillonite-kaolinite, having a minimum content of:</p> <ul style="list-style-type: none"> — 40 % of illite — 10 % of montmorillonite — 8 % of kaolinite <p><i>Characterisation of the active substance</i></p> <p>Illite:</p> <p>CAS number 106958-53-6</p> $K(Al,Fe)_2AlSi_3O_{10}(OH)_2 \cdot H_2O$ <p>Montmorillonite:</p> <p>CAS number 1318-93-0</p> $Nax[(Al2-xMgx)Si_4O_{10}(OH)_2]$ <p>Kaolinite:</p> <p>CAS number 1318-74-7</p> $Al_2(OH)_4(SiO_5)$ <p>Iron (structural) 10 % average</p> <p>Free of asbestos</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Characterisation of the feed additive:</p> <ul style="list-style-type: none"> — X-ray diffraction (XRD) together with — X-ray fluorescence (XRF). 	Chickens for fattening and minor poultry species for fattening.	—	5 000	50 000	<ol style="list-style-type: none"> 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 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. 3. In the labelling of the additive and premixtures containing it, the following shall be indicated: 'The additive illite-montmorillonite-kaolinite is rich in (inert) iron'. 4. The total amount of different uses of illite-montmorillonite-kaolinite in complete feedingstuff shall not exceed the permitted maximum level for the relevant species or category of animals. 5. The instructions for use shall indicate the following: <ul style="list-style-type: none"> — 'The simultaneous oral use with macrolides shall be avoided'. 	24 January 2029
		<p>Cattle for fattening and minor ruminants for fattening</p> <p>Pigs for fattening and weaned piglets</p>	—	5 000	20 000			

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Technological additives: anticaking agents								
1g599	Illite-montmorillonite-kaolinite	<p><i>Additive composition</i></p> <p>Preparation of a natural mixture of illite- montmorillonite-kaolinite, having a minimum content of:</p> <ul style="list-style-type: none"> — 40 % of illite — 10 % of montmorillonite — 8 % of kaolinite <p><i>Characterisation of the active substance</i></p> <p>Illite:</p> <p>CAS number 106958-53-6</p> $K(Al,Fe)_2AlSi_3O_{10}(OH)_2 \cdot H_2O$ <p>Montmorillonite:</p> <p>CAS number 1318-93-0</p> $Nax[(Al2-xMgx)Si4O10] (OH)_2$ <p>Kaolinite:</p> <p>CAS number 1318-74-7</p> $Al_2(OH)_4(SiO_5)$ <p>Iron (structural) 10 % average</p> <p>Free of asbestos</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Characterisation of the feed additive:</p> <ul style="list-style-type: none"> — X-ray diffraction (XRD) together with — X-ray fluorescence (XRF). 	Chickens for fattening and minor poultry species for fattening.	—	5 000	50 000	<ol style="list-style-type: none"> 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 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. 3. In the labelling of the additive and premixtures containing it, the following shall be indicated: 'The additive illite-montmorillonite-kaolinite is rich in (inert) iron'. 4. The total amount of different uses of illite-montmorillonite-kaolinite in complete feedingstuff shall not exceed the permitted maximum level for the relevant species or category of animals. 5. The instructions for use shall indicate the following: <ul style="list-style-type: none"> — 'The simultaneous oral use with macrolides shall be avoided'. 	24 January 2029
		All other animal species and categories	—	5 000	20 000			

⁽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) 2019/11**of 3 January 2019****concerning the authorisation of the preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for sows, suckling piglets, weaned piglets, pigs for fattening, and amending Regulations (EC) No 252/2006, (EC) No 943/2005 and (EC) No 1200/2005 (holder of authorisation DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. z o.o.)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The preparation of *Enterococcus faecium* NCIMB 10415 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for piglets by Commission Regulation (EC) No 252/2006 ⁽³⁾, for pigs for fattening by Commission Regulation (EC) No 943/2005 ⁽⁴⁾ and for sows by Commission Regulation (EC) No 1200/2005 ⁽⁵⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for sows, weaned piglets, suckling piglets and pigs for fattening. The applicant requested that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 June 2015 ⁽⁶⁾ and 21 February 2018 ⁽⁷⁾ that, under the proposed conditions of use, the preparation of *Enterococcus faecium* NCIMB 10415 does not have an adverse effect on animal health, human health or the environment. The Authority considered that the additive has the potential to improve performance parameters in suckling piglets, weaned piglets, pigs for fattening and sows. 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 *Enterococcus faecium* NCIMB 10415 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) Therefore, Regulations (EC) No 252/2006, (EC) No 943/2005 and (EC) No 1200/2005 should be amended accordingly.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ Commission Regulation (EC) No 252/2006 of 14 February 2006 concerning the permanent authorisations of certain additives in feedingstuffs and the provisional authorisations of new uses of certain additives already authorised in feedingstuffs (OJ L 44, 15.2.2006, p. 3).

⁽⁴⁾ Commission Regulation (EC) No 943/2005 of 21 June 2005 concerning the permanent authorisation of additives in feedingstuffs (OJ L 159, 22.6.2005, p. 6).

⁽⁵⁾ Commission Regulation (EC) No 1200/2005 of 26 July 2005 concerning the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs (OJ L 195, 27.7.2005, p. 6).

⁽⁶⁾ EFSA Journal 2015; 13(7):4158.

⁽⁷⁾ EFSA Journal 2018; 16(3):5201.

- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The 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

Amendment to Regulation (EC) No 252/2006

Regulation (EC) No 252/2006 is amended as follows:

- (1) Article 1 is deleted;
- (2) Annex I is deleted.

Article 3

Amendment to Regulation (EC) No 943/2005

Regulation (EC) No 943/2005 is amended as follows:

- (1) Article 1 is deleted;
- (2) Annex I is deleted.

Article 4

Amendment to Regulation (EC) No 1200/2005

In Annex II to Regulation (EC) No 1200/2005, the entry E 1705 on *Enterococcus faecium* NCIMB 10415 is deleted.

Article 5

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 24 July 2019 in accordance with the rules applicable before 24 January 2019 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 6

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, 3 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: gut flora stabilisers.

4b1705	DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. z o.o.	<i>Enterococcus faecium</i> NCIMB 10415	<p><i>Additive composition</i></p> <p>Preparation of <i>Enterococcus faecium</i> NCIMB 10415 containing a minimum of:</p> <ul style="list-style-type: none"> — coated form (with shellac): 2 × 10¹⁰ CFU/g additive, or — other coated forms: 1 × 10¹⁰ CFU/g additive, or — granulated non-coated form: 3,5 × 10¹⁰ CFU/g additive. <p><i>Characterisation of the active substance</i></p> <p>Viable cells of <i>Enterococcus faecium</i> NCIMB 10415</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration: spread plate method using bile esculin azide agar (EN 15788)</p> <p>Identification: Pulsed- Field Gel Electrophoresis (PFGE)</p>	Sows	—	7 × 10 ⁸	—	<ol style="list-style-type: none"> 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 be administered to pregnant and lactating sows and simultaneously to the suckling piglets 3. For use in weaned piglets until approximately 35 kg. 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 reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment. 	24 January 2029
				Suckling piglets		1 × 10 ⁹	—		
				Weaned piglets Pigs for fattening		3,5 × 10 ⁸	—		

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2019/12
of 3 January 2019
concerning the authorisation of L-arginine as a feed additive for all animal species
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 two applications were submitted for the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 10741P and by *Escherichia coli* NITE BP-02186 as a feed additive for use in feed and in water for drinking for all animal species. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The applications concern the authorisation of L-arginine produced by *Corynebacterium glutamicum* KCCM 10741P as a feed additive for all animal species to be classified in the additive category 'nutritional additives' and of L-arginine produced by *Escherichia coli* NITE BP-02186 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', and in the additive category 'sensory additives', functional group 'flavouring compounds'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 18 April 2018 ⁽²⁾ and 19 April 2018 ⁽³⁾ that, under the proposed conditions of use, L-arginine produced by *Escherichia coli* NITE BP-02186 and by *Corynebacterium glutamicum* KCCM 10741P does not have an adverse effect on animal health, consumer health or the environment and that no safety concerns for users would arise provided that appropriate protective measures are taken.
- (5) The Authority also concluded that the additive is an effective source of the amino acid arginine for all animal species and that for the supplemental L-arginine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority expressed in its opinions a concern over potential nutritional imbalances of when L-arginine is administered as amino acid via water for drinking. However, no maximum content for L-arginine is proposed by the Authority. Moreover, the Authority recommends supplementation with L-arginine in appropriate amounts. Thus, in the case of supplementation with L-arginine as amino acid via drinking water it is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids.
- (6) As regards the use as flavouring, the Authority states that no further demonstration of efficacy is necessary when used at the recommended dose. The use of L-arginine as flavouring compound is not authorised in water for drinking. At the recommended dose, L-arginine as flavouring compound is unlikely to pose any concern for the dietary supply with all the essential and conditionally essential amino acids.
- (7) 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.
- (8) The assessment of L-arginine 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.
- (9) The fact that the use of the L-arginine is not authorised as flavouring in water for drinking does not preclude its use in compound feed which is administered via water.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2018;16(5):5276

⁽³⁾ EFSA Journal 2018;16(5):5277

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

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

1. The substances L-arginine produced by *Corynebacterium glutamicum* KCCM 10741P and L-arginine produced by *Escherichia coli* NITE BP-02186 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 a feed additive in animal nutrition subject to the conditions laid down in that Annex.

2. The substance L-arginine produced by *Escherichia coli* NITE BP-02186 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

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, 3 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

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

Category of nutritional additives. Functional group: amino acids, their salts and analogues.

3c363	—	L-arginine	<p><i>Additive composition</i></p> <p>Powder with a minimum content of L-arginine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water</p> <p><i>Characterisation of the active substance</i></p> <p>L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced by fermentation with <i>Escherichia coli</i> NITE BP-02186.</p> <p>Chemical formula: $C_6H_{14}N_4O_2$</p> <p>CAS number: 74-79-3</p> <p><i>Analytical method ⁽¹⁾</i></p> <p>For the identification of L-arginine in the feed additive:</p> <p>— Food Chemical Codex 'L-arginine monograph'</p> <p>For the quantification of arginine in the feed additive and water:</p> <p>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)</p>	All animal species				<ol style="list-style-type: none"> 1. L-arginine may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. 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. 4. The moisture content shall be indicated on the label of the additive. 5. Declaration to be made on the label of the additive and premixture: 'The supplementation with L-arginine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 	24 January 2029
-------	---	------------	---	--------------------	--	--	--	--	-----------------

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 %			
			<p>For the quantification of arginine in premixtures, compound feed and feed materials:</p> <p>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009</p>					6. For users of the additive and premixture, 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 by such procedures and measures, the additive and premixture shall be used with personal protective equipment, including breathing protection.	
3c362	—	L-arginine	<p><i>Additive composition</i></p> <p>Powder with a minimum content of L-arginine of 98 % (on a dry matter basis) and a maximum content of 0,5 % water</p> <p><i>Characterisation of the active substance</i></p> <p>L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM10741P</p> <p>Chemical formula: C₆H₁₄N₄O₂</p> <p>CAS number: 74-79-3</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>For the identification of L-arginine in the feed additive:</p> <p>— Food Chemical Codex 'L-arginine monograph'</p>	All animal species				<ol style="list-style-type: none"> 1. L-arginine may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. 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. 4. Declaration to be made on the label of the additive and premixture: 'The supplementation with L-arginine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 	24 January 2029

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 %			
			<p>For the quantification of arginine in the feed additive and water:</p> <p>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)</p> <p>For the quantification of arginine in premixtures, compound feed and feed materials:</p> <p>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009</p>					5. For users of the additive and premixture, 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 by such procedures and measures, the additive and premixture shall be used with personal protective equipment, including breathing protection.	

Category: Sensory additives. Functional group: Flavouring compounds

3c363	—	L-Arginine	<p><i>Additive composition</i></p> <p>Powder with a minimum content of L-arginine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water</p> <p><i>Characterisation of the active substance</i></p> <p>L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced by fermentation with</p> <p>— <i>Escherichia coli</i> NITE BP-02186</p> <p>Chemical formula: C₆H₁₄N₄O₂</p> <p>CAS number 74-79-3</p> <p>FLAVIS No 17.003</p>	All animal species	—	—	—	<ol style="list-style-type: none"> 1. L-arginine may be placed on the market and used as an additive consisting of a preparation 2. The additive shall be incorporated into the feed in the form of a premixture. 3. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 4. The moisture content shall be indicated on the label of the additive. 	24 January 2029
-------	---	------------	---	--------------------	---	---	---	--	-----------------

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 %			
			<p><i>Method of analysis</i> ⁽¹⁾</p> <p>For the identification of L-arginine in the feed additive:</p> <p>— Food Chemical Codex 'L-arginine monograph'</p> <p>For the quantification of arginine in the feed additive</p> <p>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)</p> <p>For the quantification of arginine in premixtures, compound feed and feed materials:</p> <p>— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009</p>					<p>5. On the label of the additive and premixture the following shall be indicated:</p> <p>'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'</p> <p>6. For users of the additive and premixture, 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 by such procedures and measures, the additive and premixture shall be used with personal protective equipment, including breathing protection.</p>	

⁽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>

CORRIGENDA**Corrigendum to Regulation (EU) 2018/231 of the European Central Bank of 26 January 2018 on statistical reporting requirements for pension funds (ECB/2018/2)**

(Official Journal of the European Union L 45 of 17 February 2018)

On page 13, in the last sub-heading of Table 1c:

for: 'Data required to be provided on an annual (!) basis',

read: 'Assets data required to be provided on a quarterly basis and liabilities data required to be provided on an annual (!) basis'.

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



Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN