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⁽¹⁾ Text with EEA relevance.

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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.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/238

of 15 February 2018

concerning the authorisation of disodium 5'-ribonucleotides, disodium 5'-guanylate and disodium 5'-inosinate as feed additives for all animal species**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Disodium 5'-ribonucleotides, disodium 5'-guanylate and disodium 5'-inosinate ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested those additives be classified in the additive category 'sensory additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003. Lately the applicant withdrew the application for water for drinking.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 March 2014 ⁽³⁾ that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of the substances concerned in feed is similar to that in food. The Authority has already concluded that for food the substances concerned are efficacious, as they increase the food smell or palatability. Therefore, that conclusion can be extrapolated for feed. The applicant withdrew the application for water for drinking. However, the substances concerned can be used within compound feeds which are subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures and on the labelling of compound feeds and feed materials.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ EFSA Journal 2014;12(3):3606.

- (6) The Authority also concluded that in the absence of data the substances concerned should be considered as potentially hazardous to workers by skin, eyes and mucous membranes or inhalation exposure. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied except for the substances concerned produced by fermentation. The applicant asked for the authorisation of the substances concerned produced by fermentation and RNA hydrolysis. The lack of information on the production strains does not allow to assess the safety of the substances concerned produced by fermentation despite they are '*per se*' safe. Accordingly, the use of the substances concerned should be authorised as specified in the Annex to this Regulation and the authorisation of those additives produced by fermentation should be denied.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Article 2

Denial

The authorisation of disodium 5'-ribonucleotides, disodium 5'-guanylate and disodium 5'-inosinate produced by fermentation is denied.

Article 3

Transitional measures

1. The substances specified in the Annex and the substances mentioned in Article 2, and premixtures containing those substances and which are produced and labelled before 15 December 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex and the substances mentioned in Article 2 which are produced and labelled before 15 September 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex and the substances mentioned in Article 2 which are produced and labelled before 15 September 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

*Article 4***Entry into force**

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

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

Done at Brussels, 15 February 2018.

For the Commission

The President

Jean-Claude JUNKER

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: Sensory additives. Functional group: Flavouring compounds									
2b635	—	Disodium 5'-ribonucleotide	<i>Additive composition</i> Disodium 5'-ribonucleotides <i>Characterisation of the active substance</i> Disodium 5'-ribonucleotides: a mixture of disodium 5'-guanylate (GMP) and disodium 5'-inosinate (IMP). Produced by RNA hydrolysis Purity: min.: 97 % assay Chemical formula: — C ₁₀ H ₁₁ N ₄ O ₈ P · nH ₂ O — C ₁₀ H ₁₂ N ₅ Na ₂ O ₈ P · nH ₂ O <i>Method of analysis</i> ⁽¹⁾ For the identification of GMP and IMP in the feed additive: JECFA monograph, Specifications for food additives: Disodium 5'-Ribonucleotides. For the determination of GMP and IMP in the feed additive and premixtures of flavourings: High performance Liquid Chromatography coupled to UV detection (HPLC-UV).	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance or the combination of disodium 5'-ribonucleotide (2b635), disodium 5'-guanylate (2b627) and disodium 5'-inosinate (2b631) shall be: 50 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance or the combination of disodium 5'-ribonucleotide, disodium 5'-guanylate and disodium 5'-inosinate of complete feedingstuff with a moisture content of 12 %: 50 mg/kg'.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the following content of the active substance or the combination of disodium 5'-ribonucleotide, disodium 5'-guanylate and disodium 5'-inosinate in complete feedingstuff with a moisture content of 12 % is exceeded: 50 mg/kg. 6. 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.	
2b627	—	Disodium 5'-guanylate	<i>Additive composition</i> Disodium 5'-guanylate (GMP) <i>Characterisation of the active substance</i> Disodium 5'-guanylate Produced by RNA hydrolysis	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			Purity: min.: 97 % assay Chemical formula: $C_{10}H_{12}N_5Na_2O_8P \cdot n H_2O$ CAS number: 5550-12-9 <i>Method of analysis</i> ⁽¹⁾ For the identification of GMP in the feed additive: JECFA monograph, Specifications for food additives: Disodium 5'-Ribonucleotides. For the determination of GMP in the feed additive and premixtures of flavourings: High performance Liquid Chromatography coupled to UV detection (HPLC-UV).					3. The recommended maximum content of the active substance or the combination of disodium 5'-ribonucleotide (2b635), disodium 5'-guanylate (2b627) and disodium 5'-inosinate (2b631) shall be: 50 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance or the combination of disodium 5'-ribonucleotide, disodium 5'-guanylate and disodium 5'-inosinate of complete feedingstuff with a moisture content of 12 %: 50 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the following content of the active substance or the combination of disodium 5'-ribonucleotide disodium 5'-guanylate and disodium 5'-inosinate in complete feedingstuff with a moisture content of 12 % is exceeded: 50 mg/kg.	

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 %			
								6. 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.	
2b631	—	Disodium 5'-inosinate	<i>Additive composition</i> Disodium 5'-inosinate (IMP) <i>Characterisation of the active substance</i> Disodium 5'-inosinate Produced by RNA hydrolysis Purity: min. 97 % assay Chemical formula: C ₁₀ H ₁₁ N ₄ O ₈ P · nH ₂ O CAS number 4691-65-0 <i>Method of analysis</i> ⁽¹⁾ For the identification of IMP in the feed additive: JECFA monograph, Specifications for food additives: Disodium 5'-Ribonucleotides.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance or the combination of disodium 5'-ribonucleotide (2b635), disodium 5'-guanylate (2b627) and disodium 5'-inosinate (2b631) shall be: 50 mg/kg of complete feedingstuff with a moisture content of 12 %.	15.3.2028

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 %			
			For the determination of IMP in the feed additive and premixtures of flavourings: High performance Liquid Chromatography coupled to UV detection (HPLC-UV).					4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance or the combination of disodium 5'-ribonucleotide, disodium 5'-guanylate and disodium 5'-inosinate of complete feedingstuff with a moisture content of 12 %: 50 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the following content of the active substance or the combination of disodium 5'-ribonucleotide, disodium 5'-guanylate and disodium 5'-inosinate in complete feedingstuff with a moisture content of 12 % is exceeded: 50 mg/kg. 6. 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.	

(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) 2018/239**of 15 February 2018****concerning the authorisation of methyl N-methylantranilate and methylantranilate as feed additives for all animal species except avian species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances methyl N-methylantranilate and methylantranilate were authorised without a time limit in accordance with Directive 70/524/EEC as feeds additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of methyl N-methylantranilate and methylantranilate as feed additives for all animal species except for avian species. The applicant requested those additives to be classified in the additive category 'sensory 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 opinion of 15 November 2011 ⁽³⁾ that, under the proposed conditions of use in feed, methyl N-methylantranilate and methylantranilate do not have adverse effects on animal health, human health or the environment. The Authority has concluded that, since methyl N-methylantranilate and methylantranilate are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy was necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for water for drinking, however, it should be possible to use the substances concerned within compound feeds which are subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures and on the labelling of feed materials and compound feed.
- (6) The Authority concluded that methyl N-methylantranilate and methylantranilate are possible eye and respiratory irritants. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of methyl N-methylantranilate and methylantranilate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2011; 9(12):2441

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

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

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: Sensory additives. Functional group: Flavouring compounds									
2b09781	—	Methyl N-methylanthranilate	<i>Additive composition</i> Methyl N-methylanthranilate <i>Characterisation of the active substance</i> Methyl N-methylanthranilate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₉ H ₁₁ O ₂ N CAS number: 85-91-6 FLAVIS No 09.781 <i>Method of analysis</i> ⁽¹⁾ For the identification of methyl N-methylanthranilate in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All species except avian species	—	—	—	1. The additive shall be incorporated into the feed in the form of a pre-mixture. 2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 4 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 4 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 4 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b09715	—	Methylantranilate	<i>Additive composition</i> Methylantranilate <i>Characterisation of the active substance</i> Methylantranilate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₉ O ₂ N CAS number: 134-20-3 FLAVIS No 09.715 <i>Method of analysis</i> ⁽¹⁾ For the identification of methylantranilate in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All species except avian 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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 25 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg'.	15.3.2028

Identi- fication number of the additive	Name of the holder of authori- sation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authori- sation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
								5. The functional group, the identifica- tion number, the name and the added amount of the active sub- stance shall be indicated on the label of premixtures and on the la- belling of feed materials and com- pound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For users of the additive and pre- mixtures, feed business operators shall establish operational proce- dures and organisational measures to address potential risks by inhala- tion, dermal contact or eyes contact. Where those risks cannot be elimi- nated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equip- ment, including breathing protec- tion, safety glasses and gloves.	

(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) 2018/240**of 15 February 2018****concerning the authorisation of trimethylamine, trimethylamine hydrochloride, 3-methylbutylamine for all animal species except laying hens and 2-methoxyethyl benzene, 1,3-dimethoxybenzene, 1,4-dimethoxybenzene, 1-isopropyl-2-methoxy-4-methylbenzene as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances trimethylamine, trimethylamine hydrochloride, 3-methylbutylamine for all animal species, except laying hens and 2-methoxyethyl benzene, 1,3-dimethoxybenzene, 1,4-dimethoxybenzene, 1-isopropyl-2-methoxy-4-methylbenzene for all animal species ('the substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10 (1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation as feed additives of trimethylamine, trimethylamine hydrochloride, 3-methylbutylamine for all animal species, except laying hens and 2-methoxyethyl benzene, 1,3-dimethoxybenzene, 1,4-dimethoxybenzene, 1-isopropyl-2-methoxy-4-methylbenzene for all animal species. The applicant requested those additives to be classified in the additive category 'sensory 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 25 April 2012 ⁽³⁾ that, under the proposed conditions of use in feed, the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority has concluded that, since the substances concerned are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy was necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for water for drinking, however, it should be possible to use the substances concerned within compound feeds which are subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures and on the labelling of feed materials and compound feed.
- (6) The Authority noted that trimethylamine, trimethylamine hydrochloride, 3-methylbutylamine are recognised as being corrosive to the eye, strongly irritant or corrosive to the skin and irritant to respiratory tract. Asthma like

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2012;10(5):2678 and EFSA Journal 2012;10(5):2679.

symptoms may occur after inhalation. For 2-methoxyethyl benzene, 1,3-dimethoxy-benzene, 1,4-dimethoxy-benzene, 1-isopropyl-2-methoxy-4-methylbenzene potential hazards for skin and eye contact and respiratory exposure are recognised. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (7) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

For the Commission

The President

Jean-Claude JUNKER

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: Sensory additives. Functional group: Flavouring compounds									
2b11009	—	Trimethylamine	<i>Additive composition</i> Trimethylamine <i>Characterisation of the active substance</i> Trimethylamine Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₃ H ₉ N CAS number: 75-50-3 FLAVIS No: 11.009 <i>Method of analysis</i> ⁽¹⁾ For the determination of trimethylamine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species except laying hens	—	—	—	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b11024	—	Trimethylamine hydrochloride	<i>Additive composition</i> Trimethylamine hydrochloride <i>Characterisation of the active substance</i> Trimethylamine hydrochloride Produced by chemical synthesis Purity: min. 98.5 % Chemical formula: C ₃ H ₉ N · HCl CAS number: 593-81-7 FLAVIS No: 11.024 <i>Method of analysis</i> ⁽¹⁾ For the determination of trimethylamine hydrochloride in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species except laying hens	—	—	—	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg’.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	
2b11001	—	3-Methylbutylamine	<i>Additive composition</i> 3-Methylbutylamine <i>Characterisation of the active substance</i> 3-Methylbutylamine Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₅ H ₁₃ N CAS number: 107-85-7 FLAVIS No:11.001	All animal species except laying hens	—	—	—	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 3-methylbutylamine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for pigs and poultry, except laying hens; — 1,5 mg/kg for other species and categories. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for pigs and poultry, except laying hens; — 1,5 mg/kg for other species and categories’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for pigs and poultry, except laying hens; — 1,5 mg/kg for other species and categories.	

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 %			
								6. 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.	
2b03006	—	2-Methoxyethyl benzene	<i>Additive composition</i> 2-Methoxyethyl benzene <i>Characterisation of the active substance</i> 2-Methoxyethyl benzene Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₉ H ₁₂ O CAS number: 3558-60-9 FLAVIS No: 03.006 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-methoxyethyl benzene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories.	15.3.2028

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 %			
								4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories.’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories. 6. 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.	

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 %			
2b04016	—	1,3-Dimethoxy-benzene	<i>Additive composition</i> 1,3-Dimethoxy-benzene <i>Characterisation of the active substance</i> 1,3-Dimethoxy-benzene Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₀ O ₂ CAS number: 151-10-0 FLAVIS No: 04.016 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1,3-dimethoxy-benzene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 1 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg.	15.3.2028

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 %			
								6. For users of the additive and pre-mixtures, 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 pre-mixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	
2b04034	—	1,4-Dimethoxy-benzene	<i>Additive composition</i> 1,4-Dimethoxy-benzene <i>Characterisation of the active substance</i> 1,4-Dimethoxy-benzene Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₀ O ₂ CAS number: 150-78-7 FLAVIS No: 04.034 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1,4-dimethoxy-benzene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a pre-mixture. 2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 1 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 mg/kg'.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg. 6. 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.	
2b04043	—	1-Isopropyl-2-methoxy-4-methylbenzene	<i>Additive composition</i> 1-Isopropyl-2-methoxy-4-methylbenzene <i>Characterisation of the active substance</i> 1-Isopropyl-2-methoxy-4-methylbenzene Produced by chemical synthesis Purity: min. 98 %	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 1 mg/kg of complete feedingstuff with a moisture content of 12 %.	15.3.2028

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 %			
			Chemical formula: C ₁₁ H ₁₆ O CAS number: 1076-56-8 FLAVIS No: 04.043 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1-isopropyl-2-methoxy-4-methylbenzene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg. 6. 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.	

⁽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) 2018/241**of 15 February 2018****concerning the authorisation of piperine, 3-methylindole, indole, 2-acetylpyrrole and pyrrolidine as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances piperine, 3-methylindole, indole, 2-acetylpyrrole and pyrrolidine, ('the substances concerned') were authorised without a time limit by Directive 70/524/EEC as feeds additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested that those additives be classified in the additive category 'sensory additives'. This 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 opinion of 26 January 2016 ⁽³⁾ that, under the proposed conditions of use in feed, the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority has concluded that, since the substances concerned are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy was necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for water for drinking. However, it should be possible to use the substances concerned within compound feeds which are subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures and on the labelling of feed materials and compound feed.
- (6) The Authority noted that for the substances concerned potential hazards for skin and eye contact and respiratory exposure are recognised. Most are classified as irritating to the respiratory system. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2016;14(2):4390

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

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

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: Sensory additives. Functional group: Flavouring compounds									
2b14003	—	Piperine	<i>Additive composition</i> Piperine <i>Characterisation of the active substance</i> Piperine Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₁₇ H ₁₉ O ₃ N CAS number: 94-62-2 FLAVIS No: 14.003 <i>Method of analysis</i> ⁽¹⁾ For the determination of piperine in the feed additive and in feed flavouring premixtures: Gas chromatography coupled to a Flame Ionisation Detector (GC-FID).	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a pre-mixture. 2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 0,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,5 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 0,5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b14004	—	3-Methylindole	<i>Additive composition</i> 3-Methylindole <i>Characterisation of the active substance</i> 3-Methylindole Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₉ H ₉ N CAS number: 83-34-1 FLAVIS No:14.004 <i>Method of analysis</i> ⁽¹⁾ For the identification of 3-methylindole in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 0,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,5 mg/kg'.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 0,5 mg/kg. 6. 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.	
2b14007	—	Indole	<i>Additive composition</i> Indole <i>Characterisation of the active substance</i> Indole Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₈ H ₇ N	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			CAS number: 120-72-9 FLAVIS No: 14.007 <i>Method of analysis</i> ⁽¹⁾ For the determination of indole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. The recommended maximum content of the active substance shall be: 0,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,5 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 0,5 mg/kg. 6. 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.	

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 %			
2b14047	—	2-Acetylpyrrole	<i>Additive composition</i> 2-Acetylpyrrole <i>Characterisation of the active substance</i> 2-Acetylpyrrole Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₆ H ₇ ON CAS number 1072-83-9 FLAVIS No: 14.047 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-acetylpyrrole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: 0,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,5 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 0,5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b14064	—	Pyrrolidine	<i>Additive composition</i> Pyrrolidine <i>Characterisation of the active substance</i> Pyrrolidine Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₄ H ₉ N CAS number 123-75-1 FLAVIS No: 14.064 <i>Method of analysis</i> ⁽¹⁾ For the determination of pyrrolidine the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %.shall be: — 0,3 mg/kg for pigs and poultry, — 0,5 mg/kg for other species and categories. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry, — 0,5 mg/kg for other species and categories.'	15.3.2028

Identi- cation number of the additive	Name of the holder of authori- sation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authori- sation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
								5. The functional group, the identifica- tion number, the name and the added amount of the active sub- stance shall be indicated on the label of premixtures and on the la- belling of feed materials and com- pound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry, — 0,5 mg/kg for other species and categories. 6. For users of the additive and pre- mixtures, feed business operators shall establish operational proce- dures and organisational measures to address potential risks by inhala- tion, dermal contact or eyes contact. Where those risks cannot be elimi- nated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equip- ment, including breathing protec- tion, safety glasses and gloves.	

(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>

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concerning the authorisation of hex-3(cis)-en-1-ol, non-6-en-1-ol, oct-3-en-1-ol, non-6(cis)-enal, hex-3(cis)-enal, hept-4-enal, hex-3(cis)-enyl acetate, hex-3(cis)-enyl formate, hex-3-enyl butyrate, hex-3-enyl hexanoate, hex-3(cis)-enyl isobutyrate, citronellol, (-)-3,7-dimethyl-6-octen-1-ol, citronellal, 2,6-dimethylhept-5-enal, citronellic acid, citronellyl acetate, citronellyl butyrate, citronellyl formate, citronellyl propionate, 1-ethoxy-1-(3-hexenyloxy)ethane and hex-3-enyl isovalerate as feed additives for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances, hex-3(cis)-en-1-ol, non-6-en-1-ol, oct-3-en-1-ol, non-6(cis)-enal, hex-3(cis)-enal, hept-4-enal, hex-3(cis)-enyl acetate, hex-3(cis)-enyl formate, hex-3-enyl butyrate, hex-3-enyl hexanoate, hex-3(cis)-enyl isobutyrate, citronellol, (-)-3,7-dimethyl-6-octen-1-ol, citronellal, 2,6-dimethylhept-5-enal, citronellic acid, citronellyl acetate, citronellyl butyrate, citronellyl formate, citronellyl propionate, 1-ethoxy-1-(3-hexenyloxy)ethane and hex-3-enyl isovalerate ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested that those additives be classified in the additive category 'sensory 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 opinion of 12 July 2016 ⁽³⁾ that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority has concluded that, since the substances concerned are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy was necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for water for drinking. However, it should be possible to use the substances concerned within compound feeds which are subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, a recommended content should be indicated on the label of the additive. Where such content is exceeded, certain information should be indicated on the label of premixtures, and on the labelling of feed materials and compound feed.
- (6) The Authority concluded that hazards for the skin, eye contact and respiratory exposure are recognised. Most substances are classified as irritating to the respiratory system. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2016;14(8):4559.

- (7) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound containing the substances as specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b02056	—	Hex-3(cis)-en-1-ol	<i>Additive composition</i> Hex-3(cis)-en-1-ol <i>Characterisation of the active substance</i> Hex-3(cis)-en-1-ol Produced by chemical synthesis Purity: min. 98 % assay as sum of (Z)- and (E)-isomers; min. 92 % of (Z)-isomer Chemical formula: C ₆ H ₁₂ O CAS number: 928-96-1 FLAVIS No: 02.056 <i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3(cis)-en-1-ol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.' 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b02093	—	Non-6-en-1-ol	<i>Additive composition</i> Non-6-en-1-ol <i>Characterisation of the active substance</i> Non-6-en-1-ol Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₉ H ₁₈ O CAS number: 35854-86-5 FLAVIS No: 02.093	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 1 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of non-6-en-1-ol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL					5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg. 6. 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.	
2b02094	—	Oct-3-en-1-ol	<i>Additive composition</i> Oct-3-en-1-ol <i>Characterisation of the active substance</i> Oct-3-en-1-ol Produced by chemical synthesis	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			Purity: min. 96 % assay, as (Z)-isomer. Chemical formula: C ₈ H ₁₆ O CAS number: 20125-84-2 FLAVIS No: 02.094 <i>Method of analysis</i> (1) For the determination oct-3-en-1-ol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL					3. The recommended maximum content of the active substance shall be 1 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 mg/kg.’ 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg. 6. 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.	

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 %			
2b05059	—	Non-6(cis)-enal	<i>Additive composition</i> Non-6(cis)-enal <i>Characterisation of the active substance</i> Non-6(cis)-enal Produced by chemical synthesis Purity: min. 96 % assay; secondary component 6–9 % trans-6-nonenal Chemical formula: C ₉ H ₁₆ O CAS number: 2277-19-2 FLAVIS No: 05.059 <i>Method of analysis</i> ⁽¹⁾ For the determination non-6(cis)-enal in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.' 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg	15.3.2028

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 %			
								6. 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.	
2b05075	—	Hex-3(cis)-enal	<i>Additive composition</i> Hex-3(cis)-enal <i>Characterisation of the active substance</i> Hex-3(cis)-enal Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₆ H ₁₀ O CAS number: 6789-80-6 FLAVIS No: 05.075	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3(cis)-enal in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL					5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	
2b05085	—	Hept-4-enal	<i>Additive composition</i> Hept-4-enal <i>Characterisation of the active substance</i> Hept-4-enal Produced by chemical synthesis	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			Purity: min. 98 % as sum of (Z)- and (E)-isomers; min. 93 % of (Z)-isomer; secondary component: 2-5 % (E)- isomer. Chemical formula: C₇H₁₂O CAS number: 6728-31-0 FLAVIS No: 05.085 <i>Method of analysis</i> ⁽¹⁾ For the determination of hept-4-enal in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.’ 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	

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 %			
2b09197	—	Hex-3(cis)-enyl acetate	<i>Additive composition</i> Hex-3(cis)-enyl acetate <i>Characterisation of the active substance</i> Hex-3(cis)-enyl acetate Produced by chemical synthesis Purity: min. 98 % assay as sum of (Z)- and (E)-isomers; min. 92 % of (Z)-isomer Chemical formula: C ₈ H ₁₄ O ₂ CAS number: 3681-71-8 FLAVIS No: 09.197 <i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3(cis)-enyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.' 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b09240	—	Hex-3(cis)-enyl formate	<i>Additive composition</i> Hex-3(cis)-enyl formate <i>Characterisation of the active substance</i> Hex-3(cis)-enyl formate Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C ₇ H ₁₂ O ₂ CAS number: 33467-73-1 FLAVIS No: 09.240	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3(cis)-enyl formate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	
2b09270	—	Hex-3-enyl butyrate	<i>Additive composition</i> Hex-3-enyl butyrate <i>Characterisation of the active substance</i> Hex-3-enyl butyrate Produced by chemical synthesis	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			Purity: min. 95 % assay Chemical formula: C ₁₀ H ₁₈ O ₂ CAS number: 16491-36-4 FLAVIS No: 09.270 <i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3-enyl butyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.’ 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	

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 %			
2b09271	—	Hex-3-enyl hexanoate	<i>Additive composition</i> Hex-3-enyl hexanoate <i>Characterisation of the active substance</i> Hex-3-enyl hexanoate Produced by chemical synthesis Purity: min. 96 % assay Chemical formula: C ₁₂ H ₂₂ O ₂ CAS number: 31501-11-8 FLAVIS No: 09.271 <i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3-enyl hexanoate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.' 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b09563	—	Hex-3(cis)-enyl isobutyrate	<i>Additive composition</i> Hex-3(cis)-enyl isobutyrate <i>Characterisation of the active substance</i> Hex-3(cis)-enyl isobutyrate Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₁₀ H ₁₈ O ₂ CAS number: 41519-23-7 FLAVIS No: 09.563	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3(cis)-enyl isobutyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	
2b02011	—	Citronellol	<i>Additive composition</i> Citronellol <i>Characterisation of the active substance</i> Citronellol Produced by chemical synthesis	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			Purity: min. 90 % assay; racemate; other constituents: diunsaturated and saturated C10 alcohols, citronellyl acetate and citronellal Chemical formula: C₁₀H₂₀O CAS number: 106-22-9 FLAVIS No: 02.011 <i>Method of analysis</i> (1) For the determination of citronellol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	

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 %			
								6. 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.	
2b02229	—	(-)-3,7-Dimethyl-6-octen-1-ol	<i>Additive composition</i> (-)-3,7-Dimethyl-6-octen-1-ol <i>Characterisation of the active substance</i> (-)-3,7-Dimethyl-6-octen-1-ol Produced by chemical synthesis or derived by fractional distillation of essential oils and saponification of extracts Purity: min. 90 % assay Chemical formula: C ₁₀ H ₂₀ O CAS number: 7540-51-4 FLAVIS No: 02.229	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of (-)-3,7-dimethyl-6-octen-1-ol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories. 6. 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.	

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 %			
2b05021	—	Citronellal	<i>Additive composition</i> Citronellal <i>Characterisation of the active substance</i> Citronellal Produced by chemical synthesis Purity: min. 85 % assay. Chemical formula: C ₁₀ H ₁₈ O CAS number: 106-23-0 FLAVIS No: 05.021 <i>Method of analysis</i> ⁽¹⁾ For the determination of citronellal in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories' 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	15.3.2028

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 %			
								6. 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.	
2b05074	—	2,6-Dimethylhept-5-enal	<i>Additive composition</i> 2,6-Dimethylhept-5-enal <i>Characterisation of the active substance</i> 2,6-Dimethylhept-5-enal Produced by chemical synthesis Purity: min. 85 % assay Chemical formula: C ₉ H ₁₆ O CAS number: 106-72-9 FLAVIS No: 05.074	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 2,6-dimethylhept-5-enal in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories. 6. 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.	

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 %			
2b08036	—	Citronellic acid	<i>Additive composition</i> Citronellic acid <i>Characterisation of the active substance</i> Citronellic acid Produced by chemical synthesis Purity: min. 90 % assay Chemical formula: C ₁₀ H ₁₈ O ₂ CAS number: 502-47-6 FLAVIS No: 08.036 <i>Method of analysis</i> ⁽¹⁾ For the determination of citronellic acid in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	—	- The additive shall be incorporated into the feed in the form of a pre-mixture. - In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. - The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories'. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	15.3.2028

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 %			
								6. 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.	
2b09012	—	Citronellyl acetate	<i>Additive composition</i> Citronellyl acetate <i>Characterisation of the active substance</i> Citronellyl acetate Produced by chemical synthesis Purity: min. 92 % assay Chemical formula: C ₁₁ H ₂₂ O ₂ CAS number: 150-84-5 FLAVIS No: 09.012	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of citronellyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories. 6. 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.	

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 %			
2b09049	—	Citronellyl butyrate	<i>Additive composition</i> Citronellyl butyrate <i>Characterisation of the active substance</i> Citronellyl butyrate Produced by chemical synthesis Purity: min. 90 % assay Chemical formula: C ₁₄ H ₂₆ O ₂ CAS number: 141-16-2 FLAVIS No: 09.049 <i>Method of analysis</i> ⁽¹⁾ For the determination of citronellyl butyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	—	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. - The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories'. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	15.3.2028

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 %			
								6. 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.	
2b09078	—	Citronellyl formate	<i>Additive composition</i> Citronellyl formate <i>Characterisation of the active substance</i> Citronellyl formate Produced by chemical synthesis Purity: min. 90 % assay. Chemical formula: C ₁₁ H ₂₀ O ₂ CAS number: 105-85-1 FLAVIS No: 09.078	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of citronellyl formate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories. 6. 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.	

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 %			
2b09129	—	Citronellyl propionate	<i>Additive composition</i> Citronellyl propionate <i>Characterisation of the active substance</i> Citronellyl propionate Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C ₁₃ H ₂₄ O ₂ CAS number: 141-14-0 FLAVIS No: 09.129 <i>Method of analysis</i> ⁽¹⁾ For the determination of citronellyl propionate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	—	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. - The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 1 mg/kg for cats — 5 mg/kg for other species and categories. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 1 mg/kg for cats — 5 mg/kg for other species and categories'. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 1 mg/kg for cats — 5 mg/kg for other species and categories.	15.3.2028

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 %			
								6. 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.	
2b06081	—	1-Ethoxy-1-(3-hexenyloxy)ethane	<i>Additive composition</i> 1-Ethoxy-1-(3-hexenyloxy)ethane <i>Characterisation of the active substance</i> 1-Ethoxy-1-(3-hexenyloxy)ethane Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number: 28069-74-1 FLAVIS No: 06.081	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 1 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 1-ethoxy-1-(3-hexenyloxy)ethane in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg. 6. 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.	
2b09505	—	Hex-3-enyl isovalerate	<i>Additive composition</i> Hex-3-enyl isovalerate <i>Characterisation of the active substance</i> Hex-3-enyl isovalerate Produced by chemical synthesis	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			Purity: min. 95 % assay Chemical formula: C ₁₁ H ₂₀ O ₂ CAS number: 10032-11-8 FLAVIS No: 09.505 <i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3-enyl isovalerate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. The recommended maximum content of the active substance shall be 1 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 mg/kg.’ 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg. 6. 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.	

⁽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) 2018/243**of 15 February 2018****concerning the authorisation of 3-hydroxybutan-2-one, pentan-2,3-dione, 3,5-dimethyl cyclopentan-1,2-dione, hexan-3,4-dione, sec-butan-3-onyl acetate, 2,6,6-trimethylcyclohex-2-en-1,4-dione and 3-methylnona-2,4-dione as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances 3-hydroxybutan-2-one, pentan-2,3-dione, 3,5-dimethyl cyclopentan-1,2-dione, hexan-3,4-dione, sec-butan-3-onyl acetate, 2,6,6-trimethylcyclohex-2-en-1,4-dione and 3-methylnona-2,4-dione ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested that those additives be classified in the additive category 'sensory 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 opinion of 19 October 2016 ⁽³⁾ that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority has concluded that, since the substances concerned are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy was necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for water for drinking, however, it should be possible to use the substances concerned within compound feeds which are subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, a recommended content should be indicated on the label of the additive. Where such content is exceeded, certain information should be indicated on the label of premixtures, and on the labelling of feed materials and compound feed.
- (6) The Authority noted that hazards for the skin, eye contact and respiratory exposure are recognised. Most substances are classified as irritating to the respiratory system. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ EFSA Journal 2016;14(11):4618.

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

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b07051	—	3-Hydroxybutan-2-one	<i>Additive composition</i> 3-Hydroxybutan-2-one <i>Characterisation of the active substance</i> 3-Hydroxybutan-2-one Produced by chemical synthesis Purity: min. 96 % assay Chemical formula: C ₄ H ₈ O ₂ CAS number: 513-86-0 FLAVIS No: 07.051 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3-hydroxybutan-2-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.’ 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b07060	—	Pentan-2,3-dione	<i>Additive composition</i> Pentan-2,3-dione <i>Characterisation of the active substance</i> Pentan-2,3-dione Produced by chemical synthesis Purity: min. 93 % assay Chemical formula: C ₅ H ₈ O ₂ CAS number: 600-14-6 FLAVIS No: 07.060 <i>Method of analysis</i> ⁽¹⁾ For the determination of pentan-2,3-dione in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.'	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	
2b07076	—	3,5-Dimethyl cyclopentan-1,2-dione	<i>Additive composition</i> 3,5-dimethyl cyclopentan-1,2-dione <i>Characterisation of the active substance</i> 3,5-dimethyl cyclopentan-1,2-dione Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₇ H ₁₀ O ₂	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			CAS number: 13494-07-0 FLAVIS No: 07.076 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3,5-dimethyl cyclopentan-1,2-dione in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. The recommended maximum content of the active substance shall be 0,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,5 mg/kg.' 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 0,5 mg/kg. 6. 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.	

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 %			
2b07077	—	Hexan-3,4-dione	<i>Additive composition</i> Hexan-3,4-dione <i>Characterisation of the active substance</i> Hexan-3,4-dione Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₆ H ₁₀ O ₂ CAS number: 4437-51-8 FLAVIS No: 07.077 <i>Method of analysis</i> ⁽¹⁾ For the determination of hexan-3,4-dione in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.’ 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b09186	—	Sec-butan-3-onyl acetate	<i>Additive composition</i> Sec-butan-3-onyl acetate <i>Characterisation of the active substance</i> Sec-butan-3-onyl acetate Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₆ H ₁₀ O ₃ CAS number: 4906-24-5 FLAVIS No: 09.186 <i>Method of analysis</i> ⁽¹⁾ For the determination of sec-butan-3-onyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.'	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	
2b07109	—	2,6,6-Trimethylcyclohex-2-en-1,4-dione	<i>Additive composition</i> 2,6,6-Trimethylcyclohex-2-en-1,4-dione <i>Characterisation of the active substance</i> 2,6,6-Trimethylcyclohex-2-en-1,4-dione Produced by chemical synthesis Purity: min. 98 % assay	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			Chemical formula: C₉H₁₂O₂ CAS number: 1125-21-9 FLAVIS No: 07.109 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2,6,6-trimethylcyclohex-2-en-1,4-dione in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories.	

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 %			
								6. For users of the additive and pre-mixtures, 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 pre-mixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	
2b07184	—	3-Methylnona-2-,4-dione	<i>Additive composition</i> 3-Methylnona-2-,4-dione <i>Characterisation of the active substance</i> 3-Methylnona-2-,4-dione Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₁₀ H ₁₈ O ₂ CAS number: 113486-29-6 FLAVIS No: 07.184 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3-methylnona-2-,4-dione in the feed additive and in feed flavouring pre-mixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a pre-mixture. 2. In the directions for use of the additive and pre-mixtures, the storage and stability conditions shall be indicated. 3. The recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 % shall be: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories'.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories. 6. 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.	

(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) 2018/244**of 15 February 2018****concerning the authorisation of vanillyl acetone and 4-(4-methoxyphenyl) butan-2-one as feed additives for all animal species and the denial of 1-phenylethan-1-ol****(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 substances vanillyl acetone, 4-(4-methoxyphenyl) butan-2-one and 1-phenylethan-1-ol were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of vanillyl acetone, 4-(4-methoxyphenyl) butan-2-one and 1-phenylethan-1-ol as feed additives for all animal species. The applicant requested that those additives be classified in the additive category 'sensory 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 opinion of 12 July 2016 ⁽³⁾ that, under the proposed conditions of use, vanillyl acetone and 4-(4-methoxyphenyl) butan-2-one do not have adverse effects on animal health, human health or the environment. The Authority could not conclude on the safety of 1-phenylethan-1-ol in the terrestrial compartment. The Authority has concluded that, since vanillyl acetone and 4-(4-methoxyphenyl) butan-2-one are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy was necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for water for drinking. However, it should be possible to use vanillyl acetone and 4-(4-methoxyphenyl) butan-2-one within compound feeds which are subsequently administered via water.
- (5) Restrictions and conditions should be provided to allow better control. Since safety reasons do not require the setting of a maximum content and taking into account the re-evaluation performed by the Authority, a recommended content should be indicated on the label of the additive. Where such content is exceeded, certain information should be indicated on the label of premixtures, and on the labelling of feed materials and compound feed.
- (6) The Authority noted that, vanillyl acetone and 4-(4-methoxyphenyl) butan-2-one should be recognised as hazardous to the respiratory tract, skin and eyes and also as irritating to the respiratory system. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of vanillyl acetone and 4-(4-methoxyphenyl) butan-2-one shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2016;14(8):4557.

- (8) The assessment of 1-phenylethan-1-ol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied. The Authority could not conclude on the safety of 1-phenylethan-1-ol for the terrestrial compartment, as no experimental data was provided by the applicant and therefore application of the Ecological Structure Activity Relationships (ECOSAR) Predictive Model was not able to provide the needed parameters.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for vanillyl acetone, 4-(4-methoxyphenyl) butan-2-one and 1-phenylethan-1-ol, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation and denial.
- (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

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

Article 2

Denial

The authorisation of 1-phenylethan-1-ol, as additive belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds' is denied.

Article 3

Transitional measures

1. Vanillyl acetone, 4-(4-methoxyphenyl) butan-2-one and 1-phenylethan-1-ol and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing vanillyl acetone, 4-(4-methoxyphenyl) butan-2-one and 1-phenylethan-1-ol which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing vanillyl acetone, 4-(4-methoxyphenyl) butan-2-one and 1-phenylethan-1-ol which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 4

Entry into force

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

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

Done at Brussels, 15 February 2018.

For the Commission

The President

Jean-Claude JUNKER

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: Sensory additives. Functional group: Flavouring compounds									
2b07005	—	Vanillyl acetone	<i>Additive composition</i> Vanillyl acetone <i>Characterisation of the active substance</i> Vanillyl acetone Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C ₁₁ H ₁₄ O ₃ CAS number: 122-48-5 FLAVIS No: 07.005 <i>Method of analysis</i> ⁽¹⁾ For the determination of vanillyl acetone in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.’ 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b07029	—	4-(4-Methoxyphenyl) butan-2-one	<i>Additive composition</i> 4-(4-Methoxyphenyl) butan-2-one <i>Characterisation of the active substance</i> 4-(4-Methoxyphenyl) butan-2-one Produced by chemical synthesis Purity: min. 96 % assay Chemical formula: C ₁₁ H ₁₄ O ₂ CAS number 104-20-1 FLAVIS No 07.029 <i>Method of analysis</i> ⁽¹⁾ For the determination of 4-(4-methoxyphenyl) butan-2-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.'	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures and on the labelling of feed materials and compound feedingstuffs, if the content of the active substance in complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	

(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) 2018/245**of 15 February 2018****concerning the authorisation of menthol, d-carvone, menthyl acetate, d,l-isomenthone, 3-methyl-2-(pent-2(cis)-enyl)cyclopent-2-en-1-one, 3,5,5-trimethylcyclohex-2-en-1-one, d-fenchone, fenchyl alcohol, carvyl acetate, dihydrocarvyl acetate and fenchyl acetate as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances menthol, d-carvone, menthyl acetate, d,l-isomenthone, 3-methyl-2-(pent-2(cis)-enyl)cyclopent-2-en-1-one, 3,5,5-trimethylcyclohex-2-en-1-one, d-fenchone, fenchyl alcohol, carvyl acetate, dihydrocarvyl acetate and fenchyl acetate ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested those additives be classified in the additive category 'sensory 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 opinion of 20 April 2016 ⁽³⁾ that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority has concluded that, since the substances concerned are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for the use of the substances concerned in water for drinking.
- (5) The Authority further noted that hazards for the skin, eye contact and respiratory exposure are recognised. Most substances are classified as irritating to the respiratory system. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.
- (7) The applicant proposed use levels for the substances concerned to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe ('levels considered by the Authority'). For the purpose of official controls along the food chain, certain labelling requirements should be provided for. In particular, where the use levels exceed the levels considered by the Authority, it is appropriate to require that the label of premixtures and the labelling of feed materials and compound feed containing the substances concerned include certain information including reference to the levels considered by the Authority.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2016;14(6):4475.

- (8) The fact that the use of the substances concerned in water for drinking is not authorised does not preclude their use in compound feed which is administered via water.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

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: Sensory additives. Functional group: Flavouring compounds									
2b02015	—	Menthol	<i>Additive composition</i> Menthol <i>Characterisation of the active substance</i> Menthol Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C ₁₀ H ₂₀ O CAS number: 89-78-1 FLAVIS No: 02.015 <i>Method of analysis</i> ⁽¹⁾ For the determination of menthol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg	15.3.2028

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 %			
								6. 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.	
2b07146	—	d-Carvone	<i>Additive composition</i> d-Carvone <i>Characterisation of the active substance</i> d-Carvone Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C ₁₀ H ₁₄ O CAS number: 2244-16-8 FLAVIS No: 07.146 <i>Method of analysis</i> (1) For the determination of d-carvone in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg 6. 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.	
2b09016	—	Menthyl acetate	Additive composition Menthyl acetate Characterisation of the active substance Menthyl acetate Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C₁₂H₂₂O₂	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			CAS number: 29066-34-0 FLAVIS No: 09.016 <i>Method of analysis</i> ⁽¹⁾ For the determination of menthyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg 6. 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.	

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 %			
2b07078	—	d,l-Iso-menthone	<i>Additive composition</i> d,l-Isomenthone <i>Characterisation of the active substance</i> d,l-Isomenthone Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₁₀ H ₁₈ O CAS number: 491-07-6 FLAVIS No: 07.078 <i>Method of analysis</i> ⁽¹⁾ For the determination of d,l-isomenthone in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories.’ 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 suggested on the label of the premixture would result in exceeding the levels referred to in point 3 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories	15.3.2028

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 %			
								6. 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.	
2b07094	—	3-Methyl-2-(pent-2(cis)-enyl)cyclopent-2-en-1-one	<i>Additive composition</i> 3-Methyl-2-(pent-2(cis)-enyl)cyclopent-2-en-1-one <i>Characterisation of the active substance</i> 3-Methyl-2-(pent-2(cis)-enyl)cyclopent-2-en-1-one Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₁₁ H ₁₆ O CAS number: 488-10-8 FLAVIS No: 07.094	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 3-methyl-2-(pent-2(cis)-enyl)cyclopent-2-en-1-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 suggested on the label of the premixture would result in exceeding the levels referred to in point 3 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories. 6. 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.	

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 %			
2b07126	—	3,5,5-Tri-methylcyclohex-2-en-1-one	<i>Additive composition</i> 3,5,5-Trimethylcyclohex-2-en-1-one <i>Characterisation of the active substance</i> 3,5,5-Trimethylcyclohex-2-en-1-one Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₉ H ₁₄ O CAS number: 78-59-1 FLAVIS No: 07.126 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3,5,5-trimethylcyclohex-2-en-1-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	—	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories.' - 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 suggested on the label of the premixture would result in exceeding the levels referred to in point 3. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories	15.3.2028

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 %			
								6. 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 glove.	
2b07159	—	d-Fenchone	<i>Additive composition</i> d-Fenchone <i>Characterisation of the active substance</i> d-Fenchone Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₁₀ H ₁₆ O CAS number: 4695-62-9 FLAVIS No: 07.159 <i>Method of analysis</i> ⁽¹⁾ For the determination of d-fenchone in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories.'	15.3.2028

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 %			
								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 suggested on the label of the premixture would result in exceeding the levels referred to in point 3 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories 6. 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	

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 %			
2b02038	—	Fenchyl alcohol	<i>Additive composition</i> Fenchyl alcohol <i>Characterisation of the active substance</i> Fenchyl alcohol Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₁₀ H ₁₈ O CAS number: 1632-73-1 FLAVIS No: 02.038 <i>Method of analysis</i> ⁽¹⁾ For the determination of fenchyl alcohol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg	15.3.2028

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 %			
								6. 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.	
2b09215	—	Carvyl acetate	<i>Additive composition</i> Carvyl acetate <i>Characterisation of the active substance</i> Carvyl acetate Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₁₂ H ₁₈ O ₂ CAS number: 97-42-7 FLAVIS No: 09.215 <i>Method of analysis</i> ⁽¹⁾ For the determination of carvyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg. 6. 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.	
2b09216	—	Dihydrocarvyl acetate	<i>Additive composition</i> Dihydrocarvyl acetate <i>Characterisation of the active substance</i> Dihydrocarvyl acetate Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₁₂ H ₂₀ O ₂	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			CAS number: 20777-49-5 FLAVIS No: 09.216 <i>Method of analysis</i> ⁽¹⁾ For the determination of dihydrocarvyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL					3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg 6. 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.	

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 %			
2b09269	—	Fenchyl acetate	<i>Additive composition</i> Fenchyl acetate <i>Characterisation of the active substance</i> Fenchyl acetate Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₁₂ H ₂₀ O ₂ CAS number: 13851-11-1 FLAVIS No: 09.269 <i>Method of analysis</i> ⁽¹⁾ For the determination of fenchyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 1 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 1 mg/kg	15.3.2028

Identifica- tion number of the additive	Name of the holder of authori- sation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of pe- riod of authori- sation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
								6. For users of the additive and premix- tures, 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 re- duced to a minimum by such proce- dures and measures, the additive and premixtures shall be used with per- sonal protective equipment, includ- ing breathing protection, safety glasses and gloves.	

(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) 2018/246
of 15 February 2018
concerning the authorisation of linalool oxide as a feed additive for all animal species except fish
(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 substance linalool oxide was authorised by Directive 70/524/EEC as a feed additive for all animal species. That substance was subsequently entered in the Register of feed additives as existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of linalool oxide as a feed additive for all animal species except fish. The applicant requested that this additive be classified in the additive category 'sensory 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 opinion of 13 June 2012 ⁽³⁾ that, under the proposed conditions of use, linalool oxide does not have adverse effects on animal health, human health or the environment. In addition, as regards consumer safety, the conclusions of the opinion adopted on 5 March 2014 ⁽⁴⁾ are applicable to linalool oxide since linalool oxide belongs to the same chemical group as the substances examined in that opinion. The terminal metabolism of this additive through glucuronidation among mammals, birds and fish allows the conjugates of the additive to be rapidly excreted. The Authority has concluded that, since linalool is used in food as flavouring and its function in feed is essentially the same as in food, no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for use of linalool in water for drinking.
- (5) The Authority further concluded that, linalool oxide should be treated as potentially hazardous to the respiratory tract, skin and eyes and also as irritating to the skin. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of linalool oxide 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.
- (7) The applicant proposed use levels for linalool oxide to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe ('levels considered by the Authority'). For the purpose of official controls along the food chain, certain labelling requirements should be provided for. In particular, where the use levels exceed the levels considered by the Authority, it is appropriate to require that the label of premixtures and the labelling of feed materials and compound feed containing the substances concerned include certain information including reference to the levels considered by the Authority.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2012;10(7):2786.

⁽⁴⁾ EFSA Journal 2014;12(3):3608.

- (8) The fact that the use of the substance concerned in water for drinking is not authorised does not preclude its use in compound feed which is administered via water.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for linalool oxide, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

The substance 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

Transitional measures

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substance as specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substance as specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b13140	—	Linalool oxide	<i>Additive composition</i> Linalool oxide <i>Characterisation of the active substance</i> Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C ₁₀ H ₁₈ O ₂ CAS number: 1365-19-1 FLAVIS No: 13.140 <i>Method of analysis</i> ⁽¹⁾ For the determination of linalool oxide in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species except fish	—	—	—	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,3 mg/kg for pigs and poultry, — 0,5 mg/kg for other species and categories except fish.’ 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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,3 mg/kg for pigs and poultry, — 0,5 mg/kg for other species and categories except fish. 6. 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.	

(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) 2018/247**of 15 February 2018****concerning the authorisation of 2,4,5-trimethylthiazole, 2-isobutylthiazole, 5-(2-hydroxyethyl)-4-methylthiazole, 2-acetylthiazole, 2-ethyl-4-methylthiazole, 5,6-dihydro-2,4,6-tris(2-methylpropyl)4H-1,3,5-dithiazine and thiamine hydrochloride as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances 2,4,5-trimethylthiazole, 2-isobutylthiazole, 5-(2-hydroxyethyl)-4-methylthiazole, 2-acetylthiazole, 2-ethyl-4-methylthiazole, 5,6-dihydro-2,4,6-tris(2-methylpropyl)4H-1,3,5-dithiazine and thiamine hydrochloride ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested that those additives be classified in the additive category 'sensory 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 opinion of 13 April 2016 ⁽³⁾ that, under the proposed conditions of use, the substances concerned do not have adverse effects on animal health, human health or the environment. The Authority has concluded that, since the substances concerned are used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for use of the substances concerned in water for drinking.
- (5) The Authority further noted that for the substances concerned hazards for the skin, eye contact and respiratory exposure are recognised. Most substances are classified as irritating to the respiratory system. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.
- (7) The applicant proposed use levels for the substances concerned to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe ('levels considered by the Authority'). For the purpose of official controls along the food chain, certain labelling requirements should be provided for. In particular, where the use levels exceed the levels considered by the Authority, it is appropriate to require that the label of premixtures, and the labelling of feed materials and compound feed containing the substances concerned include certain information including reference to the levels considered by the Authority.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ EFSA Journal 2016;14(4):4441.

- (8) The fact that the use of the substance concerned in water for drinking is not authorised does not preclude its use in compound feed which is administered via water.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds' which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances belonging to, the additive category 'sensory additives' and to the functional group 'flavouring compounds' as specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances belonging to, the additive category 'sensory additives' and to the functional group 'flavouring compounds' as specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b15019	—	2,4,5-Trimethylthiazole	<i>Additive composition</i> 2,4,5-Trimethylthiazole <i>Characterisation of the active substance</i> Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₆ H ₉ NS CAS number: 13623-11-5 FLAVIS No: 15.019 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2,4,5-trimethylthiazole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b15013	—	2-Isobutylthiazole	<i>Additive composition</i> 2-Isobutylthiazole <i>Characterisation of the active substance</i> 2-Isobutylthiazole Produced by chemical synthesis Purity: min. 96 % assay Chemical formula: C ₇ H ₁₁ NS CAS number: 18640-74-9 FLAVIS No: 15.013	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 2-isobutylthiazole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	
2b15014	—	5-(2-Hydroxyethyl)-4-methylthiazole	<i>Additive composition</i> 5-(2-Hydroxyethyl)-4-methylthiazole <i>Characterisation of the active substance</i> 5-(2-Hydroxyethyl)-4-methylthiazole Produced by chemical synthesis Purity: min. 96 % assay Chemical formula: C ₆ H ₉ ONS CAS number: 137-00-8 FLAVIS No: 15.014	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 mg/kg.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 5-(2-hydroxyethyl)-4-methylthiazole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	
2b15020	—	2-Acetylthiazole	<i>Additive composition</i> 2-Acetylthiazole	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			<i>Characterisation of the active substance</i> 2-Acetylthiazole Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C₅H₅ONS CAS number: 24295-03-2 FLAVIS No: 15.020 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-acetylthiazole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	

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 %			
2b15033	—	2-Ethyl-4-methylthiazole	<i>Additive composition</i> 2-Ethyl-4- methylthiazole <i>Characterisation of the active substance</i> 2-Ethyl-4- methylthiazole Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₆ H ₉ NS CAS number:15679-12-6 FLAVIS No: 15.033 <i>Method of analysis ⁽¹⁾</i> For the determination of 2-ethyl-4- methylthiazole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b15113	—	5,6-Dihydro-2,4,6, tris(2-methylpropyl)4H-1,3,5-dithiazine	<i>Additive composition</i> 5,6-Dihydro-2,4,6, tris(2-methylpropyl)4H-1,3,5-dithiazine <i>Characterisation of the active substance</i> 5,6-Dihydro-2,4,6, tris(2-methylpropyl)4H-1,3,5-dithiazine Produced by chemical synthesis Purity: min. 87 % assay Chemical formula: C ₁₅ H ₃₁ NS ₂ CAS number: 74595-94-1 FLAVIS No: 15.113 <i>Method of analysis</i> ⁽¹⁾ For the determination of 5,6-dihydro-2,4,6, tris(2-methylpropyl)4H-1,3,5-dithiazine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	
2b16027	—	Thiamine hydrochloride	<i>Additive composition</i> Thiamine hydrochloride <i>Characterisation of the active substance</i> Thiamine hydrochloride Produced by chemical synthesis Purity: min.98 % assay Chemical formula: C ₁₂ H ₁₇ ClN ₄ OS · HCl CAS number: 67-03-8 FLAVIS No: 16.027	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 mg/kg.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of thiamine hydrochloride in the feed additive and in feed flavouring premixtures: High-Performance Liquid Chromatography (HPLC) European Pharmacopeia (Ph. Eur. 6.0, method 01/2008:0303)					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	

⁽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) 2018/248**of 15 February 2018****concerning the authorisation of 2,3-diethylpyrazine, 2,5 or 6-methoxy-3-methylpyrazine, 2-acetyl-3-ethylpyrazine, 2,3-diethyl-5-methylpyrazine, 2-(sec-butyl)-3-methoxypyrazine, 2-ethyl-3-methoxypyrazine, 5,6,7,8-tetrahydroquinoxaline, 2-ethylpyrazine and 5-methylquinoxaline as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances 2,3-diethylpyrazine, 2,5 or 6-methoxy-3-methylpyrazine, 2-acetyl-3-ethylpyrazine, 2,3-diethyl-5-methylpyrazine, 2-(sec-butyl)-3-methoxypyrazine, 2-ethyl-3-methoxypyrazine, 5,6,7,8-tetrahydroquinoxaline, 2-ethylpyrazine and 5-methylquinoxaline ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested those additives be classified in the additive category 'sensory 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 opinion of 6 December 2016 ⁽³⁾ that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. These substances increase the food smell or palatability. The Authority has concluded that since the substances concerned are used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated for feed. The applicant withdrew the application for use of the substances concerned in water for drinking.
- (5) The Authority further noted that for the substances concerned hazards for the skin, eye contact and respiratory exposure are recognised. Most substances are classified as irritating to the respiratory system. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.
- (7) The applicant proposed use levels for the substances concerned to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe ('levels considered by the Authority'). For the purpose of official controls along the food chain, certain labelling requirements should be provided for. In particular, where the use levels exceed the levels considered by the Authority, it is appropriate to require that the label of premixtures and the labelling of feed materials and compound feed containing the substances concerned include certain information including reference to the levels considered by the Authority.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2016;15(2):4671.

- (8) The fact that the use of the substances concerned in water for drinking is not authorised does not preclude their use in compound feed which is administered via water.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b14005	—	2,3-Diethylpyrazine	<i>Additive composition</i> 2,3-Diethylpyrazine <i>Characterisation of the active substance</i> 2,3-Diethylpyrazine Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₈ H ₁₂ N ₂ CAS number: 15707-24-1 FLAVIS No: 14.005 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2,3-diethylpyrazine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories’. 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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories	15.3.2028

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 %			
								6. 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.	
2b14025	—	2,5 or 6-Methoxy-3-methylpyrazine	<i>Additive composition</i> 2,5 or 6-Methoxy-3-methylpyrazine <i>Characterisation of the active substance</i> 2,5 or 6-Methoxy-3-methylpyrazine Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₆ H ₈ ON ₂ CAS number: 63450-30-6 FLAVIS No: 14.025 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2,5 or 6-methoxy-3-methylpyrazine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories'. 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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories 6. 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.	
2b14049	—	2-Acetyl-3-ethylpyrazine	<i>Additive composition</i> 2-Acetyl-3-ethylpyrazine <i>Characterisation of the active substance</i> 2-Acetyl-3-ethylpyrazine Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C₈H₁₀ON₂ CAS number: 32974-92-8 FLAVIS No: 14.049	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories’.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 2-acetyl-3-ethylpyrazine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories 6. 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.	
2b14056	—	2,3-Diethyl-5-methylpyrazine	<i>Additive composition</i> 2,3-Diethyl-5-methylpyrazine	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			<i>Characterisation of the active substance</i> 2,3-Diethyl-5-methylpyrazine Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C₉H₁₄N₂ CAS number: 18138-04-0 FLAVIS No: 14.056 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2,3-diethyl-5-methylpyrazine alcohol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories’. 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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories	

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 %			
								6. 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.	
2b14062	—	2-(sec-Butyl)-3-methoxypyrazine	<i>Additive composition</i> 2-(sec-Butyl)-3-methoxypyrazine <i>Characterisation of the active substance</i> 2-(sec-Butyl)-3-methoxypyrazine Produced by chemical synthesis Purity: min. 99 % assay Chemical formula: C ₉ H ₁₄ ON ₂ CAS number: 24168-70-5 FLAVIS No: 14.062 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-(sec-butyl)-3-methoxypyrazine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories'. 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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories 6. 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.	
2b14112	—	2-Ethyl-3-methoxypyrazine	<i>Additive composition</i> 2-Ethyl-3-methoxypyrazine <i>Characterisation of the active substance</i> 2-Ethyl-3-methoxypyrazine Produced by chemical synthesis Purity: min. 99 % assay Chemical formula: C₇H₁₀N₂O CAS number: 25680-58-4 FLAVIS No: 14.112	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,1 mg/kg for pigs and poultry — 0,5 mg/kg for other species and categories’.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 2-ethyl-3-methoxypyrazine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories 6. 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.	
2b14015	—	5,6,7,8-Tetrahydroquinoxaline	<i>Additive composition</i> 5,6,7,8-Tetrahydroquinoxaline	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 and stability conditions shall be indicated.	15.3.2028

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 %			
			<i>Characterisation of the active substance</i> 5,6,7,8-Tetrahydroquinoxaline Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C₈H₁₀N₂ CAS number: 34413-35-9 FLAVIS No: 14.015 <i>Method of analysis</i> ⁽¹⁾ For the determination of 5,6,7,8-tetrahydroquinoxaline in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories’. 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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories	

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 %			
								6. 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.	
2b14022	—	2-Ethylpyrazine	<i>Additive composition</i> 2-Ethylpyrazine <i>Characterisation of the active substance</i> 2-Ethylpyrazine Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₆ H ₈ N ₂ CAS number: 13925-00-3 FLAVIS No: 14.022 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-ethylpyrazine in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories’. 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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,1 mg/kg for pigs and poultry. — 0,5 mg/kg for other species and categories 6. 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.	
2b14028	—	5-Methylquinoxaline	<i>Additive composition</i> 5-Methylquinoxaline <i>Characterisation of the active substance</i> 5-Methylquinoxaline Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C₉H₈N₂ CAS number: 13708-12-8 FLAVIS No: 14.028	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 0,05 mg/kg for pigs and poultry — 0,08 mg/kg for other species and categories.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 5-methylquinoxaline in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 levels suggested on the label of the premixture would result in exceeding the levels referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 0,05 mg/kg for pigs and poultry. — 0,08 mg/kg for other species and categories 6. 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.	

⁽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) 2018/249**of 15 February 2018**

concerning the authorisation of taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, glycine, monosodium glutamate and L-glutamic acid as feed additives for all animal species and L-cysteine hydrochloride monohydrate for all species except cats and dogs

(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 substances taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, L-cysteine hydrochloride monohydrate, glycine, monosodium glutamate and L-glutamic acid ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned produced by fermentation, protein hydrolysis and chemical synthesis as feed additives for all animal species. The applicant requested those additives be classified in the additive category 'sensory 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 opinion of 9 April 2014 ⁽³⁾ that, under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. The lack of information on the production strains does not allow concluding on the substances concerned produced by fermentation. The Authority has concluded that, since the substances concerned are efficacious when used in food as flavourings and their function in feed is essentially the same as in food, no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated to feed. The applicant withdrew the application for the use of the substances concerned in water for drinking.
- (5) The Authority further concluded that, in the absence of data, the substances concerned should be considered as irritating to skin and eyes and as skin sensitisers. The Authority also considered that the substances concerned are irritating to the respiratory system and have the potential to produce hazardous dust. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied except for the substances concerned produced by fermentation. The lack of information on the production strains does not allow assessing their safety. Accordingly, the use of the substances concerned produced by chemical synthesis and protein hydrolysis should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2014;12(5):3670.

- (7) The applicant proposed use levels for the substances concerned to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe ('levels considered by the Authority'). For the purpose of official controls along the food chain, certain labelling requirements should be provided for. In particular, where the use levels exceed the levels considered by the Authority, it is appropriate to require that the label of premixtures and the labelling of feed materials and compound feed containing the substances concerned include certain information including reference to the levels considered by the Authority.
- (8) The fact that the use of the substances concerned in water for drinking is not authorised does not preclude their use in compound feed which is administered via water.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

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

Article 2

Transitional measures

1. The substances taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, L-cysteine hydrochloride monohydrate, glycine, monosodium glutamate and L-glutamic acid, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', and premixtures containing those substances, which are produced and labelled before 15 December 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 15 September 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 15 September 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

For the Commission

The President

Jean-Claude JUNKER

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: Sensory additives. Functional group: Flavouring compounds									
2b16056	—	Taurine	<i>Additive composition</i> Taurine <i>Characterisation of the active substance</i> Taurine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C ₂ H ₇ O ₃ NS CAS number 107-35-7 FLAVIS No 16.056 <i>Method of analysis</i> ⁽¹⁾ For identification of taurine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of taurine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Commission Regulation (EC) No 152/2009 ⁽²⁾ (Annex III, part F).	All animal species	—	—	—	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.' - 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b17001	—	Beta-alanine	Additive composition Beta-alanine Characterisation of the active substance Beta-alanine Produced by chemical synthesis or protein hydrolysis Purity: min. 97 % assay Chemical formula: C₃H₇O₂N CAS number 107-95-9 FLAVIS No 17.001	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of beta-alanine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of beta-alanine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b17002	—	L-Alanine	<i>Additive composition</i> L-Alanine <i>Characterisation of the active substance</i> L-Alanine Produced by chemical synthesis or protein hydrolysis Purity: min. 98,5 % assay Chemical formula: C ₃ H ₇ NO ₂ CAS number 56-41-7 FLAVIS No 17.002 <i>Method of analysis</i> ⁽¹⁾ For identification of L-Alanine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-alanine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b17003	—	L-Arginine	Additive composition L-Arginine Characterisation of the active substance L-Arginine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C₆H₁₄O₂N₄ CAS number 74-79-3 FLAVIS No 17.003	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of L-arginine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-arginine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b17005	—	L-Aspartic acid	<i>Additive composition</i> L-Aspartic acid <i>Characterisation of the active substance</i> L-Aspartic acid Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C ₄ H ₇ O ₄ N CAS number 56-84-8 FLAVIS No 17.005 <i>Method of analysis</i> ⁽¹⁾ For identification of L-aspartic acid in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-aspartic acid in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b17008	—	L-Histidine	Additive composition L-Histidine Characterisation of the active substance L-Histidine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C₆H₉O₂N₃ CAS number 71-00-1 FLAVIS No 17.008	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of L-histidine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-histidine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b17010	—	D,L-Isoleucine	<i>Additive composition</i> D,L-Isoleucine <i>Characterisation of the active substance</i> D,L-Isoleucine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C ₆ H ₁₃ O ₂ N CAS number 443-79-8 FLAVIS No 17.010 <i>Method of analysis</i> ⁽¹⁾ For identification of D,L-isoleucine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of D, L-isoleucine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b17012	—	L-Leucine	Additive composition L-Leucine Characterisation of the active substance L-Leucine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C₆H₁₃O₂N CAS number 61-90-5 FLAVIS No 17.012	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of L-leucine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-leucine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b17018	—	L-Phenylalanine	<i>Additive composition</i> L-Phenylalanine <i>Characterisation of the active substance</i> L-Phenylalanine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C₉H₁₁O₂N CAS number 63-91-2 FLAVIS No 17.018 <i>Method of analysis</i> ⁽¹⁾ For identification of L-phenylalanine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-phenylalanine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b17019	—	L-Proline	Additive composition L-Proline Characterisation of the active substance L-Proline Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C₅H₉O₂N CAS number 147-85-3 FLAVIS No 17.019	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of L-proline in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-proline in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b17020	—	D,L-Serine	<i>Additive composition</i> D,L-Serine <i>Characterisation of the active substance</i> D,L-Serine Produced by chemical synthesis or protein hydrolysis Purity: min. 95 % assay Chemical formula: C ₃ H ₇ NO ₃ CAS number 302-84-1 FLAVIS No 17.020 <i>Method of analysis</i> ⁽¹⁾ For identification of D,L-serine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of D, L-serine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b17022	—	L-Tyrosine	Additive composition L-Tyrosine Characterisation of the active substance L-Tyrosine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C₉H₁₁O₃N CAS number 60-18-4 FLAVIS No 17.022	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of L-tyrosine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-tyrosine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b17027	—	L-Methionine	<i>Additive composition</i> L-Methionine <i>Characterisation of the active substance</i> L-Methionine Produced by chemical synthesis or protein hydrolysis Purity: min. 98,5 % assay Chemical formula: C ₅ H ₁₁ NO ₂ S CAS number 63-68-3 FLAVIS No 17.027 <i>Method of analysis</i> ⁽¹⁾ For identification of L-methionine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-methionine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b17028	—	L-Valine	Additive composition L-Valine Characterisation of the active substance L-Valine Produced by chemical synthesis or protein hydrolysis Purity: min. 98,5 % assay Chemical formula: C₅H₁₁NO₂ CAS number 72-18-4 FLAVIS No 17.028	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of L-valine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-valine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b17033	—	L-Cysteine	<i>Additive composition</i> L-Cysteine <i>Characterisation of the active substance</i> L-Cysteine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C ₃ H ₇ O ₂ NS CAS number 52-90-4 FLAVIS No 17.033 <i>Method of analysis</i> ⁽¹⁾ For identification of L-cysteine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-cysteine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b920	—	L-Cysteine hydrochloride monohydrate	Additive composition L-Cysteine hydrochloride monohydrate Characterisation of the active substance L-Cysteine hydrochloride monohydrate Produced by chemical synthesis or protein hydrolysis Purity: min. 98,5 % assay Chemical formula: C₃H₈ClNO₂S · H₂O CAS number 7048-04-6	All animal species except cats and dogs	—	—	—	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg for all species except cats and dogs'.	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of L-cysteine hydrochloride monohydrate in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-cysteine hydrochloride monohydrate in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg for all species except cats and dogs. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b17034	—	Glycine	<i>Additive composition</i> Glycine <i>Characterisation of the active substance</i> Glycine Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C ₂ H ₅ O ₂ N CAS number 56-40-6 FLAVIS No 17.034 <i>Method of analysis</i> ⁽¹⁾ For identification of glycine in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of glycine in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: — 20 g/kg for cats and dogs; — 25 g/kg for other species and categories.’ 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 suggested on the label of the premixture would result in exceeding the levels referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: — 20 g/kg for cats and dogs; — 25 g/kg for other species and categories.	15.3.2028

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 %			
								6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	
2b621	—	Monosodium glutamate	Additive composition Monosodium glutamate Characterisation of the active substance Monosodium glutamate Produced by chemical synthesis or protein hydrolysis Purity: min. 99 % assay Chemical formula: C₅H₈ NaNO₄ · H₂O CAS number 142-47-2	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For identification of monosodium glutamate in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of monosodium glutamate in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).					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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg. 6. For additives produced from hydrolysis of animal protein, the animal species shall be indicated on the label of the additive and premixtures. 7. 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.	

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 %			
2b620	—	L-Glutamic acid	<i>Additive composition</i> L-Glutamic acid <i>Characterisation of the active substance</i> L-Glutamic acid Produced by chemical synthesis or protein hydrolysis Purity: min. 98 % assay Chemical formula: C ₅ H ₉ O ₄ N CAS number 56-86-0 <i>Method of analysis</i> ⁽¹⁾ For identification of L-glutamic acid in premixtures of flavourings: Ion-exchange chromatography with post column ninhydrin derivatisation (Ph.Eur. 6.6-2.2.56-Method 1). For the determination of L-glutamic acid in premixtures: Ion-exchange chromatography with post column ninhydrin derivatisation and photometric detection: based on Regulation (EC) No 152/2009 (Annex III, part F).	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff 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 suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 25 mg/kg.	15.3.2028

Identifica- tion number of the additive	Name of the holder of authorisa- tion	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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
								6. For additives produced from hydro- lysis of animal protein, the animal species shall be indicated on the la- bel of the additive and premixtures. 7. For users of the additive and pre- mixtures, feed business operators shall establish operational proce- dures and organisational measures to address potential risks by inhala- tion, dermal contact or eyes contact. Where those risks cannot be elimin- ated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equip- ment, including breathing protec- tion, safety glasses and gloves.	

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

(²) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2018/250**of 15 February 2018****concerning the authorisation of methyl 2-furoate, bis-(2-methyl-3-furyl) disulfide, furfural, furfuryl alcohol, 2-furanmethanethiol, S-furfuryl acetothioate, difurfuryl disulfide, methyl furfuryl sulfide, 2-methylfuran-3-thiol, methyl furfuryl disulfide, methyl 2-methyl-3-furyl disulfide and furfuryl acetate as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances methyl 2-furoate, bis-(2-methyl-3-furyl) disulfide, furfural, furfuryl alcohol, 2-furanmethanethiol, S-furfuryl acetothioate, difurfuryl disulfide, methyl furfuryl sulfide, 2-methylfuran-3-thiol, methyl furfuryl disulfide, methyl 2-methyl-3-furyl disulfide and furfuryl acetate ('substances concerned') were authorised without a time limit by Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of the substances concerned as feed additives for all animal species. The applicant requested that those additives be classified in the additive category 'sensory 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 opinion of 26 January 2016 ⁽³⁾ that under the proposed conditions of use the substances concerned do not have adverse effects on animal health, human health or the environment. These substances increase the food smell or palatability. The Authority has concluded that since the substances concerned are used in food as flavourings and their function in feed is essentially the same as in food no further demonstration of efficacy is necessary. Therefore, that conclusion can be extrapolated for feed. The applicant withdrew the application for use of the substances concerned in water for drinking.
- (5) The Authority further noted that for the substances concerned hazards for the skin, eye contact and respiratory exposure are recognised. Most substances are classified as irritating to the respiratory system. Consequently, appropriate protective measures should be taken. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2016;14(2):4389.

- (7) The applicant proposed use levels for the substances concerned to the Authority. Having regard to that proposal, the Authority considered that certain use levels are safe ('levels considered by the Authority'). For the purpose of official controls along the food chain, certain labelling requirements should be provided for. In particular, where the use levels exceed the levels considered by the Authority, it is appropriate to require that the label of premixtures and the labelling of feed materials and compound feed containing the substances concerned include certain information including reference to the levels considered by the Authority.
- (8) The fact that the use of the substance concerned in water for drinking is not authorised does not preclude its use in compound feed which is administered via water.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

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

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 15 September 2018 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2019 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing the substances as specified in the Annex which are produced and labelled before 15 March 2020 in accordance with the rules applicable before 15 March 2018 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

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, 15 February 2018.

For the Commission

The President

Jean-Claude JUNKER

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: Sensory additives. Functional group: Flavouring compounds									
2b13002	—	Methyl 2-furoate	<i>Additive composition</i> Methyl 2-furoate <i>Characterisation of the active substance</i> Methyl 2-furoate Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₆ H ₆ O ₃ CAS number: 611-13-2 FLAVIS No: 13.002 <i>Method of analysis</i> ⁽¹⁾ For the determination of methyl 2-furoate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	All animal species	—	—	—	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. - On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,5 mg/kg.' - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b13016	—	Bis-(2-methyl-3-furyl) disulfide	<i>Additive composition</i> Bis-(2-methyl-3-furyl) disulfide <i>Characterisation of the active substance</i> Bis-(2-methyl-3-furyl) disulfide Produced by chemical synthesis Purity: min. 98 % assay Chemical formula: C ₁₀ H ₁₀ O ₂ S ₂ CAS number: 28588-75-2 FLAVIS No: 13.016 <i>Method of analysis</i> ⁽¹⁾ For the determination of bis-(2-methyl-3-furyl) disulfide in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	
2b13018	—	Furfural	<i>Additive composition</i> Furfural <i>Characterisation of the active substance</i> Furfural Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C ₅ H ₄ O ₂ CAS number: 98-01-1 FLAVIS No: 13.018	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg.'	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of furfural in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL					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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg. 6. 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.	

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 %			
2b13019	—	Furfuryl alcohol	<i>Additive composition</i> Furfuryl alcohol <i>Characterisation of the active substance</i> Furfuryl alcohol Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₅ H ₆ O ₂ CAS number: 98-00-0 FLAVIS No: 13.019 <i>Method of analysis</i> ⁽¹⁾ For the determination of furfuryl alcohol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 5 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b13026	—	2-Furanmethanethiol	<i>Additive composition</i> 2-Furanmethanethiol <i>Characterisation of the active substance</i> 2-Furanmethanethiol Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₅ H ₆ OS CAS number: 98-02-2 FLAVIS No: 13.026 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-furanmethanethiol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	
2b13033	—	S-Furfuryl acetothioate	<i>Additive composition</i> S-furfuryl acetothioate <i>Characterisation of the active substance</i> S-furfuryl acetothioate Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C₇H₈O₂S CAS number: 13678-68-7 FLAVIS No: 13.033	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 mg/kg.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of S-furfuryl acetothioate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	

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 %			
2b13050	—	Difurfuryl disulfide	<i>Additive composition</i> Difurfuryl disulfide <i>Characterisation of the active substance</i> Difurfuryl disulfide Produced by chemical synthesis Purity: min. 96 % assay Chemical formula: C ₁₀ H ₁₀ O ₂ S ₂ CAS number: 4437-20-1 FLAVIS No: 13.050 <i>Method of analysis</i> ⁽¹⁾ For the determination of difurfuryl disulfide in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b13053	—	Methyl furfuryl sulfide	<i>Additive composition</i> Methyl furfuryl sulfide <i>Characterisation of the active substance</i> Methyl furfuryl sulfide Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₆ H ₈ OS CAS number: 1438-91-1 FLAVIS No: 13.053 <i>Method of analysis</i> ⁽¹⁾ For the determination of methyl furfuryl sulfide in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	
2b13055	—	2-Methylfuran-3-thiol	<i>Additive composition</i> 2-Methylfuran-3-thiol <i>Characterisation of the active substance</i> 2-Methylfuran-3-thiol Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C₅H₆OS CAS number: 28588-74-1 FLAVIS No: 13.055	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 mg/kg.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of 2-methylfuran-3-thiol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	

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 %			
2b13064	—	Methyl furfuryl disulfide	<i>Additive composition</i> Methyl furfuryl disulfide <i>Characterisation of the active substance</i> Methyl furfuryl disulfide Produced by chemical synthesis Purity: min. 95 % assay Chemical formula: C ₆ H ₈ OS ₂ CAS number: 57500-00-2 FLAVIS No: 13.064 <i>Method of analysis</i> ⁽¹⁾ For the determination of methyl furfuryl disulfide in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg.	15.3.2028

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 %			
								6. 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.	
2b13079	—	Methyl 2-methyl-3-furyl disulfide	<i>Additive composition</i> Methyl 2-methyl-3-furyl disulfide <i>Characterisation of the active substance</i> Methyl 2-methyl-3-furyl disulfide Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₆ H ₈ OS ₂ CAS number: 65505-17-1 FLAVIS No: 13.079 <i>Method of analysis</i> ⁽¹⁾ For the determination of methyl 2-methyl-3-furyl disulfide in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,05 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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3.	15.3.2028

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 %			
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,05 mg/kg. 6. 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.	
2b13128	—	Furfuryl acetate	<i>Additive composition</i> Furfuryl acetate <i>Characterisation of the active substance</i> Furfuryl acetate Produced by chemical synthesis Purity: min. 97 % assay Chemical formula: C ₇ H ₈ O ₃ CAS number: 623-17-6 FLAVIS No: 13.128	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 and stability conditions shall be indicated. 3. On the label of the additive the following shall be indicated: ‘Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 0,5 mg/kg.’	15.3.2028

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 %			
			<i>Method of analysis</i> ⁽¹⁾ For the determination of furfuryl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 premixtures where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds: 0,5 mg/kg. 6. 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.	

⁽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>

