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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.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/53

of 14 December 2016

concerning the authorisation of butan-1-ol, hexan-1-ol, octan-1-ol, nonan-1-ol, dodecan-1-ol, heptan-1-ol, decan-1-ol, pentan-1-ol, ethanol, acetaldehyde, propanal, butanal, pentanal, hexanal, octanal, decanal, dodecanal, nonanal, heptanal, undecanal, 1,1-diethoxyethane, formic acid, acetic acid, propionic acid, valeric acid, hexanoic acid, octanoic acid, decanoic acid, dodecanoic acid, oleic acid, hexadecanoic acid, tetradecanoic acid, heptanoic acid, nonanoic acid, ethyl acetate, propyl acetate, butyl acetate, hexyl acetate, octyl acetate, nonyl acetate, decyl acetate, dodecyl acetate, heptyl acetate, methyl acetate, methyl butyrate, butyl butyrate, pentyl butyrate, hexyl butyrate, octyl butyrate, ethyl decanoate, ethyl hexanoate, propyl hexanoate, pentyl hexanoate, hexyl hexanoate, methyl hexanoate, ethyl formate, ethyl dodecanoate, ethyl tetradecanoate, ethyl nonanoate, ethyl octanoate, ethyl propionate, methyl propionate, ethyl valerate, butyl valerate, ethyl hex-3-enoate, ethyl hexadecanoate, ethyl trans-2-butenate, ethyl undecanoate, butyl isovalerate, hexyl isobutyrate, methyl 2-methylbutyrate, hexyl 2-methylbutyrate, triethyl citrate, hexyl isovalerate and methyl 2-methylvalerate 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) Butan-1-ol, Hexan-1-ol, octan-1-ol, nonan-1-ol, dodecan-1-ol, heptan-1-ol, decan-1-ol, pentan-1-ol, ethanol, acetaldehyde, propanal, butanal, pentanal, hexanal, octanal, decanal, dodecanal, nonanal, heptanal, undecanal, 1,1-diethoxyethane, formic acid, acetic acid, propionic acid, valeric acid, hexanoic acid, octanoic acid, decanoic acid, dodecanoic acid, oleic acid, hexadecanoic acid, tetradecanoic acid, heptanoic acid, nonanoic acid, ethyl acetate, propyl acetate, butyl acetate, hexyl acetate, octyl acetate, nonyl acetate, decyl acetate, dodecyl acetate, heptyl acetate, methyl acetate, methyl butyrate, butyl butyrate, pentyl butyrate, hexyl butyrate, octyl butyrate, ethyl decanoate, ethyl hexanoate, propyl hexanoate, pentyl hexanoate, hexyl hexanoate, methyl hexanoate, ethyl formate, ethyl dodecanoate, ethyl tetradecanoate, ethyl nonanoate, ethyl octanoate, ethyl propionate, methyl propionate, ethyl valerate, butyl valerate, ethyl hex-3-enoate, ethyl hexadecanoate, ethyl trans-2-butenate, ethyl undecanoate, butyl isovalerate, hexyl isobutyrate, methyl 2-methylbutyrate, hexyl 2-methylbutyrate, triethyl citrate, hexyl isovalerate and methyl 2-methylvalerate hereinafter referred to as 'the substances concerned' were

⁽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).

authorised without a time limit in accordance with 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 to 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 12 March 2013 ⁽¹⁾ 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 further concluded that those substances are flavouring agents authorised in food for which the efficacy is demonstrated as the functions of the additive applied for feed use and described for food use are similar.
- (5) The Authority concluded that no safety concerns would arise for users provided that appropriate protective measures are 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. Maximum recommended contents should be set up for those substances. Those substances may be used within a compound feed subsequently administered via water.
- (7) 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.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The 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 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.

⁽¹⁾ EFSA Journal 2013;11(4):3169.

2. Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b02004	—	Butan-1-ol	<i>Additive composition</i> Butan-1-ol <i>Characterisation of the active substance</i> Butan-1-ol Produced by chemical synthesis Purity: min. 99,5 % Chemical formula: C₄H₁₀O CAS number 71-36-3 FLAVIS 02.004 <i>Method of analysis</i> ⁽¹⁾ For the determination of Butan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b02005	—	Hexan-1-ol	<i>Additive composition</i> Hexan-1-ol <i>Characterisation of the active substance</i> Hexan-1-ol Produced by chemical synthesis Purity: min. 96,5 % Chemical formula: C ₆ H ₁₄ O CAS number 111-27-3 FLAVIS 02.005 <i>Method of analysis</i> ⁽¹⁾ For the determination of Hexan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b02006	—	Octan-1-ol	<i>Additive composition</i> Octan-1-ol <i>Characterisation of the active substance</i> Octan-1-ol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₈ O CAS number 111-87-5 FLAVIS 02.006 <i>Method of analysis</i> ⁽¹⁾ For the determination of Octan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b02007	—	Nonan-1-ol	<i>Additive composition</i> Nonan-1-ol <i>Characterisation of the active substance</i> Nonan-1-ol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₉ H ₂₀ O CAS number 143-08-8 FLAVIS 02.007 <i>Method of analysis</i> ⁽¹⁾ For the determination of Nonan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b02008	—	Dodecan-1-ol	<i>Additive composition</i> Dodecan-1-ol <i>Characterisation of the active substance</i> Dodecan-1-ol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₂ H ₂₆ O CAS number 112-53-8 FLAVIS 02.008 <i>Method of analysis</i> ⁽¹⁾ For the determination of Dodecan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b02021	—	Heptan-1-ol	<i>Additive composition</i> Heptan-1-ol <i>Characterisation of the active substance</i> Heptan-1-ol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₇ H ₁₆ O CAS number 111-70-6 FLAVIS 02.021 <i>Method of analysis</i> ⁽¹⁾ For the determination of Heptan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b02024	—	Decan-1-ol	<i>Additive composition</i> Decan-1-ol <i>Characterisation of the active substance</i> Decan-1-ol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₂₂ O CAS number 112-30-1 FLAVIS 02.024 <i>Method of analysis</i> ⁽¹⁾ For the determination of Decan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b02040	—	Pentan-1-ol	<i>Additive composition</i> Pentan-1-ol <i>Characterisation of the active substance</i> Pentan-1-ol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₅ H ₁₂ O CAS number 71-41-0 FLAVIS 02.040 <i>Method of analysis</i> ⁽¹⁾ For the determination of Pentan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b02078	—	Ethanol	<i>Additive composition</i> Ethanol <i>Characterisation of the active substance</i> Ethanol Produced by chemical synthesis or enzymatic fermentation. Purity: min. 95 % Chemical formula: C ₂ H ₆ O CAS number 64-17-5 FLAVIS 02.078 <i>Method of analysis ⁽¹⁾</i> For the determination of Ethanol 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05001	—	Acetaldehyde	<i>Additive composition</i> Acetaldehyde <i>Characterisation of the active substance</i> Acetaldehyde Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₂ H ₄ O CAS number 75-07-0 FLAVIS 05.001 <i>Method of analysis</i> ⁽¹⁾ For the determination of Acetaldehyde 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05002	—	Propanal	<i>Additive composition</i> Propanal <i>Characterisation of the active substance</i> Propanal Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₃ H ₆ O CAS number 123-38-6 FLAVIS 05.002 <i>Method of analysis</i> ⁽¹⁾ For the determination of Propanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05003	—	Butanal	<i>Additive composition</i> Butanal <i>Characterisation of the active substance</i> Butanal Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₆ H ₈ O CAS number 123-72-8 FLAVIS 05.003 <i>Method of analysis</i> ⁽¹⁾ For the determination of Butanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05005	—	Pentanal	<i>Additive composition</i> Pentanal <i>Characterisation of the active substance</i> Pentanal Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₅ H ₁₀ O CAS number 110-62-3 FLAVIS 05.005 <i>Method of analysis</i> ⁽¹⁾ For the determination of Pentanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05008	—	Hexanal	<i>Additive composition</i> Hexanal <i>Characterisation of the active substance</i> Hexanal Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₆ H ₁₂ O CAS number 66-25-1 FLAVIS 05.008 <i>Method of analysis</i> ⁽¹⁾ For the determination of Hexanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05009	—	Octanal	<i>Additive composition</i> Octanal <i>Characterisation of the active substance</i> Octanal Produced by chemical synthesis Purity: min. 92 % Chemical formula: C ₈ H ₁₆ O CAS number 124-13-0 FLAVIS 05.009 <i>Method of analysis</i> ⁽¹⁾ For the determination of Octanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05010	—	Decanal	<i>Additive composition</i> Decanal <i>Characterisation of the active substance</i> Decanal Produced by chemical synthesis Purity: min. 92 % Chemical formula: C ₁₀ H ₂₀ O CAS number 112-31-2 FLAVIS 05.010 <i>Method of analysis</i> ⁽¹⁾ For the determination of Decanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05011	—	Dodecanal	<i>Additive composition</i> Dodecanal <i>Characterisation of the active substance</i> Dodecanal Produced by chemical synthesis Purity: min. 92 % Chemical formula: C ₁₂ H ₂₄ O CAS number 112-54-9 FLAVIS 05.011 <i>Method of analysis</i> ⁽¹⁾ For the determination of Dodecanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05025	—	Nonanal	<i>Additive composition</i> Nonanal <i>Characterisation of the active substance</i> Nonanal Produced by chemical synthesis Purity: min. 92 % Chemical formula: C ₉ H ₁₈ O CAS number 124-19-6 FLAVIS 05.025 <i>Method of analysis</i> ⁽¹⁾ For the determination of Nonanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05031	—	Heptanal	<i>Additive composition</i> Heptanal <i>Characterisation of the active substance</i> Heptanal Produced by chemical synthesis Purity: min. 92 % Chemical formula: C ₇ H ₁₄ O CAS number 111-71-7 FLAVIS 05.031 <i>Method of analysis</i> ⁽¹⁾ For the determination of Heptanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05034	—	Undecanal	<i>Additive composition</i> Undecanal <i>Characterisation of the active substance</i> Undecanal Produced by chemical synthesis Purity: min. 92 % Chemical formula: C ₁₁ H ₂₂ O CAS number 112-44-7 FLAVIS 05.034 <i>Method of analysis</i> ⁽¹⁾ For the determination of Undecanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b06001	—	1,1-Diethoxyethane	<i>Additive composition</i> 1,1-Diethoxyethane <i>Characterisation of the active substance</i> 1,1-Diethoxyethane Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₆ H ₁₄ O ₂ CAS number 105-57-7 FLAVIS 06.001 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1,1-Diethoxyethane 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08001	—	Formic acid	<i>Additive composition</i> Formic acid <i>Characterisation of the active substance</i> Formic acid Produced by chemical synthesis Purity: min. 95 % Chemical formula: CH ₂ O ₂ CAS number 64-18-6 FLAVIS 08.001 <i>Method of analysis</i> ⁽¹⁾ For the determination of Formic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08002	—	Acetic acid	<i>Additive composition</i> Acetic acid <i>Characterisation of the active substance</i> Acetic acid Produced by chemical synthesis Purity: min. 99,5 % Chemical formula: C ₂ H ₄ O ₂ CAS number 64-19-7 FLAVIS 08.002 <i>Method of analysis</i> ⁽¹⁾ For the determination of Acetic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
1k280	—	Propionic acid	<i>Additive composition</i> Propionic acid <i>Characterisation of the active substance</i> Propionic acid Produced by chemical synthesis Purity: min. 99,5 % Non-volatile residue ≤ 0,01 % when dried at 140 °C to constant weight. Aldehydes ≤ 0,1 % expressed as formaldehyde Chemical formula: C ₃ H ₆ O ₂ CAS number 79-09-4 FLAVIS 08.003	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. 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			<i>Method of analysis</i> ⁽¹⁾ For the determination of Propionic acid in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08007	—	Valeric acid	<i>Additive composition</i> Valeric acid <i>Characterisation of the active substance</i> Valeric acid Produced by chemical synthesis Purity: min. 99 % Chemical formula: C₅H₁₀O₂ CAS number 109-52-4 FLAVIS 08.007 <i>Method of analysis</i> ⁽¹⁾ For the determination of Valeric acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08009	—	Hexanoic acid	<i>Additive composition</i> Hexanoic acid <i>Characterisation of the active substance</i> Hexanoic acid Produced by chemical modification of extracted fats Purity: min. 98 % Chemical formula: C₆H₁₂O₂ CAS number 142-62-1 FLAVIS 08.009 <i>Method of analysis</i> ⁽¹⁾ For the determination of Hexanoic acid 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 25 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08010	—	Octanoic acid	<i>Additive composition</i> Octanoic acid <i>Characterisation of the active substance</i> Octanoic acid Produced by fermentation followed by fractional distillation. Purity: min. 97 % Chemical formula: C ₈ H ₁₆ O ₂ CAS number 124-07-2 FLAVIS 08.010 <i>Method of analysis ⁽¹⁾</i> For the determination of octanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08011	—	Decanoic acid	<i>Additive composition</i> Decanoic acid <i>Characterisation of the active substance</i> Decanoic acid Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number 334-48-5 FLAVIS 08.011 <i>Method of analysis ⁽¹⁾</i> For the determination of Decanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08012	—	Dodecanoic acid	<i>Additive composition</i> Dodecanoic acid <i>Characterisation of the active substance</i> Dodecanoic acid Produced by chemical synthesis Purity: min. 90 % Chemical formula: C ₁₂ H ₂₄ O ₂ CAS number 143-07-7 FLAVIS 08.012 <i>Method of analysis</i> ⁽¹⁾ For the determination of Dodecanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08013	—	Oleic acid	<i>Additive composition</i> Oleic acid <i>Characterisation of the active substance</i> Oleic acid Produced by chemical synthesis Purity: min. 90 % Chemical formula: C ₁₈ H ₃₄ O ₂ CAS number 112-80-1 FLAVIS 08.013 <i>Method of analysis</i> ⁽¹⁾ For the determination of Oleic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08014	—	Hexadecanoic acid	<i>Additive composition</i> Hexadecanoic acid <i>Characterisation of the active substance</i> Hexadecanoic acid Produced by chemical synthesis Purity: min. 80 % Chemical formula: C ₁₆ H ₃₂ O ₂ CAS number 57-10-3 FLAVIS 08.014 <i>Method of analysis ⁽¹⁾</i> For the determination of Hexadecanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08016	—	Tetradecanoic acid	<i>Additive composition</i> Tetradecanoic acid <i>Characterisation of the active substance</i> Tetradecanoic acid Produced by chemical synthesis Purity: min. 94 % Chemical formula: C ₁₄ H ₂₈ O ₂ CAS number 544-63-8 FLAVIS 08.016 <i>Method of analysis ⁽¹⁾</i> For the determination of Tetradecanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08028	—	Heptanoic acid	<i>Additive composition</i> Heptanoic acid <i>Characterisation of the active substance</i> Heptanoic acid Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₇ H ₁₄ O ₂ CAS number 111-14-8 FLAVIS 08.028 <i>Method of analysis</i> ⁽¹⁾ For the determination of Heptanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08029	—	Nonanoic acid	<i>Additive composition</i> Nonanoic acid <i>Characterisation of the active substance</i> Nonanoic acid Produced by chemical synthesis Purity: min. 98 % Chemical formula: C9H18O2 CAS number 112-05-0 FLAVIS 08.029 <i>Method of analysis</i> ⁽¹⁾ For the determination of Nonanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09001	—	Ethyl acetate	<i>Additive composition</i> Ethyl acetate <i>Characterisation of the active substance</i> Ethyl acetate Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₄ H ₈ O ₂ CAS number 141-78-6 FLAVIS 09.001 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl 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 25 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09002	—	Propyl acetate	<i>Additive composition</i> Propyl acetate <i>Characterisation of the active substance</i> Propyl acetate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₅ H ₁₀ O ₂ CAS number 109-60-4 FLAVIS 09.002 <i>Method of analysis</i> ⁽¹⁾ For the determination of Propyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09004	—	Butyl acetate	<i>Additive composition</i> Butyl acetate <i>Characterisation of the active substance</i> Butyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₆ H ₁₂ O ₂ CAS number 123-86-4 FLAVIS 09.004 <i>Method of analysis</i> ⁽¹⁾ For the determination of Butyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09006	—	Hexyl acetate	<i>Additive composition</i> Hexyl acetate <i>Characterisation of the active substance</i> Hexyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₂ O ₂ CAS number 142-92-7 FLAVIS 09.006 <i>Method of analysis</i> ⁽¹⁾ For the determination of Hexyl 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 25 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09007	—	Octyl acetate	<i>Additive composition</i> Octyl acetate <i>Characterisation of the active substance</i> Octyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number 112-14-1 FLAVIS 09.007 <i>Method of analysis ⁽¹⁾</i> For the determination of Octyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09008	—	Nonyl acetate	<i>Additive composition</i> Nonyl acetate <i>Characterisation of the active substance</i> Nonyl acetate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₁ H ₂₂ O ₂ CAS number 143-13-5 FLAVIS 09.008 <i>Method of analysis</i> ⁽¹⁾ For the determination of Nonyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09009	—	Decyl acetate	<i>Additive composition</i> Decyl acetate <i>Characterisation of the active substance</i> Decyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₂ H ₂₄ O ₂ CAS number 112-17-4 FLAVIS 09.009 <i>Method of analysis ⁽¹⁾</i> For the determination of Decyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09010	—	Dodecyl acetate	<i>Additive composition</i> Dodecyl acetate <i>Characterisation of the active substance</i> Dodecyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₄ H ₂₈ O ₂ CAS number 112-66-3 FLAVIS 09.010 <i>Method of analysis ⁽¹⁾</i> For the determination of Dodecyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09022	—	Heptyl acetate	<i>Additive composition</i> Heptyl acetate <i>Characterisation of the active substance</i> Heptyl acetate Produced by chemical synthesis Purity: min. 97,5 % Chemical formula: C ₉ H ₁₈ O ₂ CAS number 112-06-1 FLAVIS 09.022 <i>Method of analysis</i> ⁽¹⁾ For the determination of Heptyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09023	—	Methyl acetate	<i>Additive composition</i> Methyl acetate <i>Characterisation of the active substance</i> Methyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₃H₆O₂ CAS number 79-20-9 FLAVIS 09.023 <i>Method of analysis</i> ⁽¹⁾ For the determination of Methyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09038	—	Methyl butyrate	<i>Additive composition</i> Methyl butyrate <i>Characterisation of the active substance</i> Methyl butyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₅ H ₁₀ O ₂ CAS number 623-42-7 FLAVIS 09.038 <i>Method of analysis</i> ⁽¹⁾ For the determination of Methyl butyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09042	—	Butyl butyrate	<i>Additive composition</i> Butyl butyrate <i>Characterisation of the active substance</i> Butyl butyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₆ O ₂ CAS number 109-21-7 FLAVIS 09.042 <i>Method of analysis</i> ⁽¹⁾ For the determination of Butyl butyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09044	—	Pentyl butyrate	<i>Additive composition</i> Pentyl butyrate <i>Characterisation of the active substance</i> Pentyl butyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₉ H ₁₈ O ₂ CAS number 540-18-1 FLAVIS 09.044 <i>Method of analysis</i> ⁽¹⁾ For the determination of Pentyl butyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09045	—	Hexyl butyrate	<i>Additive composition</i> Hexyl butyrate <i>Characterisation of the active substance</i> Hexyl butyrate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number 2639-63-6 FLAVIS 09.045 <i>Method of analysis ⁽¹⁾</i> For the determination of Hexyl butyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09046	—	Octyl butyrate	<i>Additive composition</i> Octyl butyrate <i>Characterisation of the active substance</i> Octyl butyrate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₂ H ₂₄ O ₂ CAS number 110-39-4 FLAVIS 09.046 <i>Method of analysis</i> ⁽¹⁾ For the determination of Octyl butyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09059	—	Ethyl decanoate	<i>Additive composition</i> Ethyl decanoate <i>Characterisation of the active substance</i> Ethyl decanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₂ H ₂₄ O ₂ CAS number 110-38-3 FLAVIS 09.059 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl decanoate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09060	—	Ethyl hexanoate	<i>Additive composition</i> Ethyl hexanoate <i>Characterisation of the active substance</i> Ethyl hexanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₆ O ₂ CAS number 123-66-0 FLAVIS 09.060 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09061	—	Propyl hexanoate	<i>Additive composition</i> Propyl hexanoate <i>Characterisation of the active substance</i> Propyl hexanoate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₉H₁₈O₂ CAS number 626-77-7 FLAVIS 09.061 <i>Method of analysis</i> ⁽¹⁾ For the determination of Propyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09065	—	Pentyl hexanoate	<i>Additive composition</i> Pentyl hexanoate <i>Characterisation of the active substance</i> Pentyl hexanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₁ H ₂₂ O ₂ CAS number 540-07-8 FLAVIS 09.065 <i>Method of analysis</i> ⁽¹⁾ For the determination of Pentyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09066	—	Hexyl hexanoate	<i>Additive composition</i> Hexyl hexanoate <i>Characterisation of the active substance</i> Hexyl hexanoate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₂ H ₂₄ O ₂ CAS number 6378-65-0 FLAVIS 09.066 <i>Method of analysis ⁽¹⁾</i> For the determination of Hexyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09069	—	Methyl hexanoate	<i>Additive composition</i> Methyl hexanoate <i>Characterisation of the active substance</i> Methyl hexanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₇ H ₁₄ O ₂ CAS number 106-70-7 FLAVIS 09.069 <i>Method of analysis</i> ⁽¹⁾ For the determination of Methyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09072	—	Ethyl formate	<i>Additive composition</i> Ethyl formate <i>Characterisation of the active substance</i> Ethyl formate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₃ H ₆ O ₂ CAS number 109-94-4 FLAVIS 09.072 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl formate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09099	—	Ethyl dodecanoate	<i>Additive composition</i> Ethyl dodecanoate <i>Characterisation of the active substance</i> Ethyl dodecanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₄ H ₂₈ O ₂ CAS number 106-33-2 FLAVIS 09.099 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl dodecanoate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09104	—	Ethyl tetradecanoate	<i>Additive composition</i> Ethyl tetradecanoate <i>Characterisation of the active substance</i> Ethyl tetradecanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₆ H ₃₂ O ₂ CAS number 124-06-1 FLAVIS 09.104 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl tetradecanoate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09107	—	Ethyl nonanoate	<i>Additive composition</i> Ethyl nonanoate <i>Characterisation of the active substance</i> Ethyl nonanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₁ H ₂₂ O ₂ CAS number 123-29-5 FLAVIS 09.107 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl nonanoate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09111	—	Ethyl octanoate	<i>Additive composition</i> Ethyl octanoate <i>Characterisation of the active substance</i> Ethyl octanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number 106-32-1 FLAVIS 09.111 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl octanoate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09121	—	Ethyl propionate	<i>Additive composition</i> Ethyl propionate <i>Characterisation of the active substance</i> Ethyl propionate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₅ H ₁₀ O ₂ CAS number 105-37-3 FLAVIS 09.121 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl propionate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09134	—	Methyl propionate	<i>Additive composition</i> Methyl propionate <i>Characterisation of the active substance</i> Methyl propionate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₄H₈O₂ CAS number 554-12-1 FLAVIS 09.134 <i>Method of analysis</i> ⁽¹⁾ For the determination of Methyl propionate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09147	—	Ethyl valerate	<i>Additive composition</i> Ethyl valerate <i>Characterisation of the active substance</i> Ethyl valerate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₇ H ₁₄ O ₂ CAS number 539-82-2 FLAVIS 09.147 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl valerate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09148	—	Butyl valerate	<i>Additive composition</i> Butyl valerate <i>Characterisation of the active substance</i> Butyl valerate Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₉ H ₁₈ O ₂ CAS number 591-68-4 FLAVIS 09.148 <i>Method of analysis</i> ⁽¹⁾ For the determination of Butyl valerate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09191	—	Ethyl hex-3-enoate	<i>Additive composition</i> Ethyl hex-3-enoate <i>Characterisation of the active substance</i> Ethyl hex-3-enoate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₈ H ₁₄ O ₂ CAS number 2396-83-0 FLAVIS 09.191 <i>Method of analysis</i> ⁽¹⁾ For the identification of Ethyl hex-3-enoate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09193	—	Ethyl hexadecanoate	<i>Additive composition</i> Ethyl hexadecanoate <i>Characterisation of the active substance</i> Ethyl hexadecanoate Produced by chemical synthesis Purity: min. 99 % Chemical formula: $C_{18}H_{36}O_2$ CAS number 628-97-7 FLAVIS 09.193 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl hexadecanoate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09248	—	Ethyl trans-2-butenolate	<i>Additive composition</i> Ethyl trans-2-butenolate <i>Characterisation of the active substance</i> Ethyl trans-2-butenolate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₆ H ₁₀ O ₂ CAS number 623-70-1 FLAVIS 09.248 <i>Method of analysis</i> ⁽¹⁾ For the identification of Ethyl trans-2-butenolate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09274	—	Ethyl undecanoate	<i>Additive composition</i> Ethyl undecanoate <i>Characterisation of the active substance</i> Ethyl undecanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₁₃H₂₆O₂ CAS number 627-90-7 FLAVIS 09.274 <i>Method of analysis</i> ⁽¹⁾ For the determination of Ethyl undecanoate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09449	—	Butyl isovalerate	<i>Additive composition</i> Butyl isovalerate <i>Characterisation of the active substance</i> Butyl isovalerate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₉ H ₁₈ O ₂ CAS number 109-19-3 FLAVIS 09.449 <i>Method of analysis</i> ⁽¹⁾ For the identification of Butyl isovalerate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09478	—	Hexyl isobutyrate	<i>Additive composition</i> Hexyl isobutyrate <i>Characterisation of the active substance</i> Hexyl isobutyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number 2349-07-7 FLAVIS 09.478 <i>Method of analysis</i> ⁽¹⁾ For the identification of Hexyl isobutyrate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09483	—	Methyl 2-methylbutyrate	<i>Additive composition</i> Methyl 2-methylbutyrate <i>Characterisation of the active substance</i> Methyl 2-methylbutyrate Produced by chemical synthesis Purity: min. 92 % Chemical formula: C ₆ H ₁₂ O ₂ CAS number 868-57-5 FLAVIS 09.483 <i>Method of analysis</i> ⁽¹⁾ For the identification of Methyl 2-methylbutyrate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09507	—	Hexyl 2-methylbutyrate	<i>Additive composition</i> Hexyl 2-methylbutyrate <i>Characterisation of the active substance</i> Hexyl 2-methylbutyrate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₁₁H₂₂O₂ CAS number 10032-15-2 FLAVIS 09.507 <i>Method of analysis</i> ⁽¹⁾ For the identification of Hexyl 2-methylbutyrate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09512	—	Triethyl citrate	<i>Additive composition</i> Triethyl citrate <i>Characterisation of the active substance</i> Triethyl citrate Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₁₂ H ₂₀ O ₇ CAS number 77-93-0 FLAVIS 09.512 <i>Method of analysis</i> ⁽¹⁾ For the determination of Triethyl citrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09529	—	Hexyl isovalerate	<i>Additive composition</i> Hexyl isovalerate <i>Characterisation of the active substance</i> Hexyl isovalerate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₁₁ H ₂₂ O ₂ CAS number 10032-13-0 FLAVIS 09.529 <i>Method of analysis</i> ⁽¹⁾ For the identification of Hexyl isovalerate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09549	—	Methyl 2-methylvalerate	<i>Additive composition</i> Methyl 2-methylvalerate <i>Characterisation of the active substance</i> Methyl 2-methylvalerate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₇ H ₁₄ O ₂ CAS number 2177-77-7 FLAVIS 09.549 <i>Method of analysis</i> ⁽¹⁾ For the identification of Methyl 2-methylvalerate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	

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

COMMISSION IMPLEMENTING REGULATION (EU) 2017/54

of 14 December 2016

concerning the authorisation of 2-methylpropan-1-ol, isopentanol, 3,7-dimethyloctan-1-ol, 2-ethylhexan-1-ol, 2-methylpropanal, 3-methylbutanal, 2-methylbutyraldehyde, 3-methylbutyric acid, 2-methylvaleric acid, 2-ethylbutyric acid, 2-methylbutyric acid, 2-methylheptanoic acid, 4-methylnonanoic acid, 4-methyloctanoic acid, isobutyl acetate, isobutyl butyrate, 3-methylbutyl hexanoate, 3-methylbutyl dodecanoate, 3-methylbutyl octanoate, 3-methylbutyl propionate, 3-methylbutyl formate, glyceryl tributyrate, isobutyl isobutyrate, isopentyl isobutyrate, isobutyl isovalerate, isopentyl 2-methylbutyrate, 2-methylbutyl isovalerate and 2-methylbutyl butyrate 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) 2-Methylpropan-1-ol, isopentanol, 3,7-dimethyloctan-1-ol, 2-ethylhexan-1-ol, 2-methylpropanal, 3-methylbutanal, 2-methylbutyraldehyde, 3-methylbutyric acid, 2-methylvaleric acid, 2-ethylbutyric acid, 2-methylbutyric acid, 2-methylheptanoic acid, 4-methylnonanoic acid, 4-methyloctanoic acid, isobutyl acetate, isobutyl butyrate, 3-methylbutyl hexanoate, 3-methylbutyl dodecanoate, 3-methylbutyl octanoate, 3-methylbutyl propionate, 3-methylbutyl formate, glyceryl tributyrate, isobutyl isobutyrate, isopentyl isobutyrate, isobutyl isovalerate, isopentyl 2-methylbutyrate, 2-methylbutyl isovalerate and 2-methylbutyl butyrate, hereinafter referred to as 'the substances concerned' were authorised without a time limit in accordance with 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 to 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 17 October 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 further concluded that those substances are flavouring agents authorised in food for which the efficacy is demonstrated as the functions of the additive applied for feed use and described for food use are similar.
- (5) The Authority concluded that no safety concerns would arise for users provided that appropriate protective measures are 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 2012;10(10):2927.

- (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. Maximum recommended contents should be set up for those substances. Those substances may be used within a compound feed subsequently administered via water.
- (7) 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.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The 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 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b02001	—	2-Methylpropan-1-ol	<i>Additive composition</i> 2-Methylpropan-1-ol <i>Characterisation of the active substance</i> 2-Methylpropan-1-ol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₄H₁₀O CAS number 78-83-1 FLAVIS 02.001 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Methylpropan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b02003	—	Isopentanol	<i>Additive composition</i> Isopentanol <i>Characterisation of the active substance</i> Isopentanol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₅ H ₁₂ O CAS number 123-51-3 FLAVIS 02.003 <i>Method of analysis</i> ⁽¹⁾ For the determination of Isopentanol 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b02026	—	3,7-Dimethyloctan-1-ol	<i>Additive composition</i> 3,7-Dimethyloctan-1-ol <i>Characterisation of the active substance</i> 3,7-Dimethyloctan-1-ol Produced by chemical synthesis Purity: min. 90 % Chemical formula: C ₁₀ H ₂₂ O CAS number 106-21-8 FLAVIS 02.026 <i>Method of analysis</i> ⁽¹⁾ For the identification of 3,7-Dimethyloctan-1-ol 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b02082	—	2-Ethylhexan-1-ol	<i>Additive composition</i> 2-Ethylhexan-1-ol <i>Characterisation of the active substance</i> 2-Ethylhexan-1-ol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₈ H ₁₈ O CAS number 104-76-7 FLAVIS 02.082 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Ethylhexan-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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b05004	—	2-Methylpropanal	<i>Additive composition</i> 2-Methylpropanal <i>Characterisation of the active substance</i> 2-Methylpropanal Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₄H₈O CAS number 78-84-2 FLAVIS 05.004 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Methylpropanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b05006	—	3-Methylbutanal	<i>Additive composition</i> 3-Methylbutanal <i>Characterisation of the active substance</i> 3-Methylbutanal Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₅ H ₁₀ O CAS number 590-86-3 FLAVIS 05.006 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3-Methylbutanal 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b05049	—	2-Methylbutyraldehyde	<i>Additive composition</i> 2-Methylbutyraldehyde <i>Characterisation of the active substance</i> 2-Methylbutyraldehyde Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₅ H ₁₀ O CAS number 96-17-3 FLAVIS 05.049 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Methylbutyraldehyde 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08008	—	3-Methylbutyric acid	<i>Additive composition</i> 3-Methylbutyric acid <i>Characterisation of the active substance</i> 3-Methylbutyric acid Produced by chemical synthesis Purity: min. 99 % Chemical formula: C₅H₁₀O₂ CAS number 503-74-2 FLAVIS 08.008 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3-Methylbutyric acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b08031	—	2-Methylvaleric acid	<i>Additive composition</i> 2-Methylvaleric acid <i>Characterisation of the active substance</i> 2-Methylvaleric acid Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₆ H ₁₂ O ₂ CAS number 97-61-0 FLAVIS 08.031 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Methylvaleric acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b08045	—	2-Ethylbutyric acid	<i>Additive composition</i> 2-Ethylbutyric acid <i>Characterisation of the active substance</i> 2-Ethylbutyric acid Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₆ H ₁₂ O ₂ CAS number 88-09-5 FLAVIS 08.045 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Ethylbutyric acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b08046	—	2-Methylbutyric acid	<i>Additive composition</i> 2-Methylbutyric acid <i>Characterisation of the active substance</i> 2-Methylbutyric acid Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₅ H ₁₀ O ₂ CAS number 116-53-0 FLAVIS 08.046 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Methylbutyric acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b08047	—	2-Methylheptanoic acid	<i>Additive composition</i> 2-Methylheptanoic acid <i>Characterisation of the active substance</i> 2-Methylheptanoic acid Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₈ H ₁₆ O ₂ CAS number 1188-02-9 FLAVIS 08.047 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Methylheptanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b08062	—	4-Methylnonanoic acid	<i>Additive composition</i> 4-Methylnonanoic acid <i>Characterisation of the active substance</i> 4-Methylnonanoic acid Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number 45019-28-1 FLAVIS 08.062 <i>Method of analysis ⁽¹⁾</i> For the identification of 4-Methylnonanoic acid 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b08063	—	4-Methyloctanoic acid	<i>Additive composition</i> 4-Methyloctanoic acid <i>Characterisation of the active substance</i> 4-Methyloctanoic acid Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₉ H ₁₈ O ₂ CAS number 54947-74-9 FLAVIS 08.063 <i>Method of analysis</i> ⁽¹⁾ For the determination of 4-Methyloctanoic acid 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09005	—	Isobutyl acetate	<i>Additive composition</i> Isobutyl acetate <i>Characterisation of the active substance</i> Isobutyl acetate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₆H₁₂O₂ CAS number 110-19-0 FLAVIS 09.005 <i>Method of analysis</i> ⁽¹⁾ For the determination of Isobutyl 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09043	—	Isobutyl butyrate	<i>Additive composition</i> Isobutyl butyrate <i>Characterisation of the active substance</i> Isobutyl butyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₆ O ₂ CAS number 539-90-2 FLAVIS 09.043 <i>Method of analysis</i> ⁽¹⁾ For the determination of Isobutyl butyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09070	—	3-Methylbutyl hexanoate	<i>Additive composition</i> 3-Methylbutyl hexanoate <i>Characterisation of the active substance</i> 3-Methylbutyl hexanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₁ H ₂₂ O ₂ CAS number 2198-61-0 FLAVIS 09.070 <i>Method of analysis</i> ⁽¹⁾ For the identification of 3-Methylbutyl hexanoate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09103	—	3-Methylbutyl dodecanoate	<i>Additive composition</i> 3-Methylbutyl dodecanoate <i>Characterisation of the active substance</i> 3-Methylbutyl dodecanoate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₁₇H₃₄O₂ CAS number 6309-51-9 FLAVIS 09.103 <i>Method of analysis</i> ⁽¹⁾ For the identification of 3-Methylbutyl dodecanoate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09120	—	3-Methylbutyl octanoate	<i>Additive composition</i> 3-Methylbutyl octanoate <i>Characterisation of the active substance</i> 3-Methylbutyl octanoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₁₃H₂₆O₂ CAS number 2035-99-6 FLAVIS 09.120 <i>Method of analysis ⁽¹⁾</i> For the identification of 3-Methylbutyl octanoate 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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. 4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09136	—	3-Methylbutyl propionate	<i>Additive composition</i> 3-Methylbutyl propionate <i>Characterisation of the active substance</i> 3-Methylbutyl propionate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₆ O ₂ CAS number 105-68-0 FLAVIS 09.136 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3-Methylbutyl propionate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09162	—	3-Methylbutyl formate	<i>Additive composition</i> 3-Methylbutyl formate <i>Characterisation of the active substance</i> 3-Methylbutyl formate Produced by chemical synthesis Purity: min. 92 % Chemical formula: C ₆ H ₁₂ O ₂ CAS number 110-45-2 FLAVIS 09.162 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3-Methylbutyl formate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09211	—	Glyceryl tri- butyrate	<i>Additive composition</i> Glyceryl tributyrate <i>Characterisation of the active substance</i> Glyceryl tributyrate Produced by chemical syn- thesis Purity: min. 99 % Chemical formula: C ₁₅ H ₂₆ O ₆ CAS number 60-01-5 FLAVIS 09.211 <i>Method of analysis</i> ⁽¹⁾ For the determination of Glyceryl tributyrate 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 incorpor- ated 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 con- tent of 12 %. 4. On the label of the additive, the recommended maximum con- tent of the active substance in complete feed shall be indicated. 5. Where the maximum recom- mended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active sub- stance shall be indicated on the labelling of the premixtures, feed materials and compounds fee- dingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09417	—	Isobutyl isobutyrate	<i>Additive composition</i> Isobutyl isobutyrate <i>Characterisation of the active substance</i> Isobutyl isobutyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₆ O ₂ CAS number 97-85-8 FLAVIS 09.417 <i>Method of analysis</i> ⁽¹⁾ For the determination of Isobutyl isobutyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	
2b09419	—	Isopentyl isobutyrate	<i>Additive composition</i> Isopentyl isobutyrate <i>Characterisation of the active substance</i> Isopentyl isobutyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₉ H ₁₈ O ₂ CAS number 2050-01-3 FLAVIS 09.419 <i>Method of analysis</i> ⁽¹⁾ For the determination of Isopentyl isobutyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09472	—	Isobutyl isovalerate	<i>Additive composition</i> Isobutyl isovalerate <i>Characterisation of the active substance</i> Isobutyl isovalerate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₉ H ₁₈ O ₂ CAS number 589-59-3 FLAVIS 09.472 <i>Method of analysis</i> ⁽¹⁾ For the determination of Isobutyl isovalerate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09530	—	Isopentyl 2-methylbutyrate	<i>Additive composition</i> Isopentyl 2-methylbutyrate <i>Characterisation of the active substance</i> Isopentyl 2-methylbutyrate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number 27625-35-0 FLAVIS 09.530 <i>Method of analysis ⁽¹⁾</i> For the determination of Isopentyl 2-methylbutyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09531	—	2-Methylbutyl isovalerate	<i>Additive composition</i> 2-Methylbutyl isovalerate <i>Characterisation of the active substance</i> 2-Methylbutyl isovalerate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₂₀ O ₂ CAS number 2445-77-4 FLAVIS 09.531 <i>Method of analysis (1)</i> For the determination of 2-Methylbutyl isovalerate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	
2b09659	—	2-Methylbutyl butyrate	<i>Additive composition</i> 2-Methylbutyl butyrate <i>Characterisation of the active substance</i> 2-Methylbutyl butyrate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₉ H ₁₈ O ₂ CAS number 51115-64-1 FLAVIS 09.659 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-Methylbutyl butyrate 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 recommended maximum content of the active substance in complete feed shall be indicated. 5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compounds feedingstuff.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators, shall establish operational procedures and appropriate organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment	

(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) 2017/55
of 14 December 2016

concerning the authorisation of octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien-2-one, nonan-3-one, decan-2-one and isopropyl tetradecanoate 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) Octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien-2-one, nonan-3-one, decan-2-one and isopropyl tetradecanoate were authorised without a time limit in accordance with 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 octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien-2-one, nonan-3-one, decan-2-one, isopropyl tetradecanoate as feed additives 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 opinion of 20 October 2015 ⁽³⁾ that, under the proposed conditions of use in feed octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien-2-one, nonan-3-one, decan-2-one, isopropyl tetradecanoate do not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien-2-one, nonan-3-one, decan-2-one, isopropyl tetradecanoate in feed is similar to that on food. The Authority has already concluded that for food those substances are efficacious, as it increases the food smell or palatability. The Authority could not conclude on the safety of octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien-2-one, nonan-3-one, decan-2-one, isopropyl tetradecanoate used in water for drinking. However, those substances can be used within a compound feed subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. For practical reasons and taking into account the re-evaluation performed by the Authority, maximum recommended contents should be set up. Where the recommended content of the additive in complete feedingstuff is exceeded, the identification number of the feed additive, its name and added amount should be indicated on the label of premixtures, 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 feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2015;13(11):4268.

- (6) The Authority concluded that in the absence of data on user safety, octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien- 2-one, nonan-3-one, decan-2-one, isopropyl tetradecanoate should be considered as irritant to skin, eyes and respiratory tract and as a skin sensitiser. 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 octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien-2-one, nonan-3-one, decan-2-one, isopropyl tetradecanoate 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 octan-2-ol, isopropanol, pentan-2-ol, octan-3-ol, heptan-2-one, pentan-2-one, 6-methyl-hepta-3,5-dien-2-one, nonan-3-one, decan-2-one, isopropyl tetradecanoate 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 as specified in the Annex and premixtures containing those substances, which are produced and labelled before 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b02022	—	Octan-2-ol	<i>Additive composition</i> Octan-2-ol <i>Characterisation of the active substance</i> Octan-2-ol Produced by chemical synthesis Purity: min 97 % C₈H₁₈O CAS No 123-96-6 FLAVIS No:02.022 <i>Methods of Analysis</i> ⁽¹⁾ For the determination of octan-2-ol 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 shall be: for pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. - 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; — 1,5 mg/kg for other species and categories.'	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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.	
2b02079	—	Isopropanol	<i>Additive composition</i> Isopropanol <i>Characterisation of the active substance</i> Isopropanol Produced by chemical synthesis Purity: min. 99,7 %	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: 25 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: C ₃ H ₈ O CAS No 67-63-0 FLAVIS No: 02.079 <i>Method of analysis</i> ⁽¹⁾ For the determination of isopropanol 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 %: 25 mg/kg' 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 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.	
2b02088	—	Pentan-2-ol	<i>Additive composition</i> Pentan-2-ol <i>Characterisation of the active substance</i> Pentan-2-ol Produced by chemical synthesis Purity: min. 97,9 % Chemical formula: C ₅ H ₁₂ O	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: for pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			CAS No 6032-29-7 FLAVIS No: 02.088 <i>Method of analysis</i> ⁽¹⁾ For the determination of pentan-2-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 pigs and poultry; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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.	
2b02098	—	Octan-3-ol	Additive composition Octan-3-ol	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			<i>Characterisation of the active substance</i> Octan-3-ol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₈H₁₈O CAS No 589-98-0 FLAVIS No:02.098 <i>Method of analysis</i> ⁽¹⁾ For the determination of octan-3-ol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.				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: for pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 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 %: — 1 mg/kg for pigs and poultry; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 1 mg/kg for pigs and poultry; — 1,5 mg/kg for other species and categories.	

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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.	
2b07002	—	Heptan-2-one	<i>Additive composition</i> Heptan-2-one <i>Characterisation of the active substance</i> Heptan-2-one Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₇ H ₁₄ O CAS No 110-43-0 FLAVIS No: 07.002 <i>Method of analysis ⁽¹⁾</i> For the determination heptan-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: for piglets: 4 mg/kg, for chickens for fattening and laying hens: 3 mg/kg, for cats: 2 mg/kg and for other species and categories: 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 %: — 4 mg/kg for piglets; — 3 mg/kg for chickens for fattening and laying hens; — 2 mg/kg for cats; — 5 mg/kg for other species and categories'	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 4 mg/kg for piglets; — 3 mg/kg for chickens for fattening and laying hens; — 2 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.	
2b07054	—	Pentan-2-one	<i>Additive composition</i> Pentan-2-one <i>Characterisation of the active substance</i> Pentan-2-one	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.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₅H₁₀O CAS No 107-87-9 FLAVIS No: 07.054 <i>Method of analysis</i> ⁽¹⁾ For the determination of pentan-2-one 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: for piglets: 4 mg/kg, for chickens for fattening and laying hens: 3 mg/kg, for cats: 2 mg/kg and for other species and categories: 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 %: — 4 mg/kg for piglets; — 3 mg/kg for chickens for fattening and laying hens; — 2 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 labelling of the pre-mixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 4 mg/kg for piglets; — 3 mg/kg for chickens for fattening and laying hens; — 2 mg/kg for cats; — 5 mg/kg for other species and categories'	

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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.	
2b07099	—	6-Methyl-hepta- 3,5-dien- 2-one	<i>Additive composition</i> 6-Methyl- hepta- 3,5-dien- 2-one <i>Characterisation of the active substance</i> 6-Methyl- hepta- 3,5-dien- 2-one Produced by chemical synthesis Purity: min. 96 % Chemical formula: C ₈ H ₁₂ O CAS No 1604-28-0 FLAVIS No: 07.099 <i>Method of analysis ⁽¹⁾</i> For the determination of 6-methyl- hepta- 3,5-dien- 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: for pigs and poultry: 0,3 mg/kg, and for other species and categories: 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 %: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories'	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the pre-mixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 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 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.	
2b07113	—	Nonan- 3-one	<i>Additive composition</i> Nonan- 3- one <i>Characterisation of the active substance</i> Nonan- 3- one 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 pre-mixtures, the storage and stability conditions shall be indicated. 3. The recommended maximum content of the active substance shall be: pigs and poultry: 0,3 mg/kg, for fish: 0,05 mg/kg and for other species and categories: 0,5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Purity: min. 95,9 % Chemical formula: C ₉ H ₁₈ O CAS No 925-78-0 FLAVIS No: 07.113 <i>Method of analysis</i> ⁽¹⁾ For the determination of nonan- 3- one 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 %: — 0,3 mg/kg for pigs and poultry; — 0,05 mg/kg for fish; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 0,3 mg/kg for pigs and poultry; — 0,05 mg/kg for fish; — 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)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b07150	—	Decan- 2 -one	<i>Additive composition</i> Decan- 2 -one <i>Characterisation of the active substance</i> Decan- 2 -one Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₁₀H₂₀O CAS No 693-54-9 FLAVIS No: 07.150 <i>Method of analysis</i> ⁽¹⁾ For the determination of decan- 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: for pigs and poultry: 0,3 mg/kg, and for other species and categories: 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 %: — 0,3 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 0,3 mg/kg for pigs and poultry; — 0,5 mg/kg for other species and categories	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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.	
2b09105	—	Isopropyl tetradecanoate	<i>Additive composition</i> Isopropyl tetradecanoate <i>Characterisation of the active substance</i> Isopropyl tetradecanoate Produced by chemical synthesis Purity: min. 99 % Chemical formula: $C_{17}H_{34}O_2$ CAS No 110-27-0 FLAVIS No 09.105 <i>Method of analysis ⁽¹⁾</i> For the determination of isopropyl tetradecanoate 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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) 2017/56
of 14 December 2016**

concerning the authorisation of lactic acid, 4-oxovaleric acid, succinic acid, fumaric acid, ethyl acetoacetate, ethyl lactate, butyl lactate, ethyl 4-oxovalerate, diethyl succinate, diethyl malonate, butyl-O-butyryllactate, hex-3-enyl lactate, hexyl lactate, butyro-1,4-lactone, decano-1,5-lactone, undecano-1,5-lactone, pentano-1,4-lactone, nonano-1,5-lactone, octano-1,5-lactone, heptano-1,4-lactone and hexano-1,4-lactone 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) Lactic acid, 4-oxovaleric acid, succinic acid, fumaric acid, ethyl acetoacetate, ethyl lactate, butyl lactate, ethyl 4-oxovalerate, diethyl succinate, diethyl malonate, butyl-O-butyryllactate, hex-3-enyl lactate, hexyl lactate, butyro-1,4-lactone, decano-1,5-lactone, undecano-1,5-lactone, pentano-1,4-lactone, nonano-1,5-lactone, octano-1,5-lactone, heptano-1,4-lactone and hexano-1,4-lactone ('the substances concerned') were authorised without a time limit in accordance with 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 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 17 October 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 further concluded that the function of the substances concerned in feed is similar to that on food. The Authority has already concluded that for food the substances concerned are efficacious, as it increases the food smell or palatability. Therefore, that conclusion can be extrapolated for feed. The Authority is not in a position to evaluate the use of the substances concerned in water for drinking. However, those substances 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, compound feeds and feed materials.
- (6) The Authority concluded that the substances concerned are considered as potentially hazardous to the respiratory tract skin, eyes and skin sensitisers. 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 2012;10(10):2928.

- (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.
- (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 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b08004	—	Lactic acid	<i>Additive composition</i> Lactic acid <i>Characterisation of the active substance</i> Lactic acid Produced by chemical synthesis Purity: min. 95 % Chemical formula: $C_3H_6O_3$ CAS number 598-82-3 and 50-21-5 for DL-lactic acid 79-33-4 for L-lactic acid FLAVIS No 08.004 <i>Method of analysis</i> ⁽¹⁾ For the determination of lactic 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 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 shall be: 5 mg/kg of complete feedingstuff with a moisture content of 12 %. - 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’. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b08023	—	4-Oxovaleric acid	<i>Additive composition</i> 4-Oxovaleric acid <i>Characterisation of the active substance</i> 4-Oxovaleric acid Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₅ H ₈ O ₃ CAS number 123-76-2 FLAVIS No 08.023 <i>Method of analysis</i> ⁽¹⁾ For the determination of 4-oxovaleric acid 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b08024	—	Succinic acid	<i>Additive composition</i> Succinic acid <i>Characterisation of the active substance</i> Succinic acid Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₄ H ₆ O ₄ CAS number 110-15-6 FLAVIS No 08.024 <i>Method of analysis</i> ⁽¹⁾ For the determination of succinic acid 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b08025	—	Fumaric acid	<i>Additive composition</i> Fumaric acid <i>Characterisation of the active substance</i> Fumaric acid Produced by chemical synthesis Purity: min. 99,5 % Chemical formula: C ₄ H ₄ O ₄ CAS number 110-17-8 FLAVIS No 08.025 <i>Method of analysis</i> ⁽¹⁾ For the determination of fumaric acid 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09402	—	Ethyl acetoacetate	<i>Additive composition</i> Ethyl acetoacetate <i>Characterisation of the active substance</i> Ethyl acetoacetate Produced by chemical synthesis Purity: min. 97,5 % Chemical formula: C ₆ H ₁₀ O ₃ CAS number 141-97-9 FLAVIS No 09.402 <i>Method of analysis</i> ⁽¹⁾ For the determination of ethyl acetoacetate 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09433	—	Ethyl lactate	<i>Additive composition</i> Ethyl lactate <i>Characterisation of the active substance</i> Ethyl lactate Produced by chemical synthesis Purity: min. 97 % Chemical formula: $C_5H_{10}O_3$ CAS number 97-64-3 FLAVIS No 09.433 <i>Method of analysis</i> ⁽¹⁾ For the determination of ethyl lactate 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: 125 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 %: 125 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 125 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09434	—	Butyl lactate	<i>Additive composition</i> Butyl lactate <i>Characterisation of the active substance</i> Butyl lactate Produced by chemical synthesis Purity: min. 95 % Chemical formula: $C_7H_{14}O_3$ CAS number 138-22-7 FLAVIS No 09.434 <i>Method of analysis</i> ⁽¹⁾ For the determination of butyl lactate 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09435	—	Ethyl 4-oxovalerate	<i>Additive composition</i> Ethyl 4-oxovalerate <i>Characterisation of the active substance</i> Ethyl 4-oxovalerate Produced by chemical synthesis Purity: min. 98 % Chemical formula: $C_7H_{12}O_3$ CAS number 539-88-8 FLAVIS No 09.435 <i>Method of analysis</i> ⁽¹⁾ For the determination of ethyl 4-oxovalerate 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09444	—	Diethyl succinate	<i>Additive composition</i> Diethyl succinate <i>Characterisation of the active substance</i> Diethyl succinate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₄ O ₄ CAS number 123-25-1 FLAVIS No 09.444 <i>Method of analysis</i> ⁽¹⁾ For the determination of diethyl succinate 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09490	—	Diethyl malonate	<i>Additive composition</i> Diethyl malonate <i>Characterisation of the active substance</i> Diethyl malonate Produced by chemical synthesis Purity: min. 97 % Chemical formula: $C_7H_{12}O_4$ CAS number 105-53-3 FLAVIS No 09.490 <i>Method of analysis</i> ⁽¹⁾ For the determination of diethyl malonate 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09491	—	Butyl-O-butyryllactate	<i>Additive composition</i> Butyl-O-butyryllactate <i>Characterisation of the active substance</i> Butyl-O-butyryllactate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₁₁ H ₂₀ O ₄ CAS number 7492-70-8 FLAVIS No 09.491 <i>Method of analysis</i> ⁽¹⁾ For the determination of butyl-O-butyryllactate 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09545	—	Hex-3-enyl lactate	<i>Additive composition</i> Hex-3-enyl lactate <i>Characterisation of the active substance</i> Hex-3-enyl lactate Produced by chemical synthesis Purity: min. 96 % Chemical formula: $C_9H_{16}O_3$ CAS number 61931-81-5 FLAVIS No 09.545 <i>Method of analysis</i> ⁽¹⁾ For the determination of hex-3-enyl lactate 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09580	—	Hexyl lactate	<i>Additive composition</i> Hexyl lactate <i>Characterisation of the active substance</i> Hexyl lactate Produced by chemical synthesis Purity: min. 95 % Chemical formula: $C_9H_{18}O_3$ CAS number 20279-51-0 FLAVIS No 09.580 <i>Method of analysis</i> ⁽¹⁾ For the determination of hexyl lactate 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b10006	—	Butyro-1,4-lactone	<i>Additive composition</i> Butyro-1,4-lactone <i>Characterisation of the active substance</i> Butyro-1,4-lactone Produced by chemical synthesis Purity: min. 98 % Chemical formula: $C_4H_6O_2$ CAS number 96-48-0 FLAVIS No 10.006 <i>Method of analysis</i> ⁽¹⁾ For the determination of butyro-1,4-lactone 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b10007	—	Decano-1,5-lactone	<i>Additive composition</i> Decano-1,5-lactone <i>Characterisation of the active substance</i> Decano-1,5-lactone Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₁₈ O ₂ CAS number 705-86-2 FLAVIS No 10.007 <i>Method of analysis</i> ⁽¹⁾ For the determination of decano-1,5-lactone 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b10011	—	Undecano-1,5-lactone	<i>Additive composition</i> Undecano-1,5-lactone <i>Characterisation of the active substance</i> Undecano-1,5-lactone Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₁ H ₂₀ O ₂ CAS number 710-04-3 FLAVIS No 10.011 <i>Method of analysis ⁽¹⁾</i> For the determination of undecano-1,5-lactone 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b10013	—	Pentano-1,4-lactone	<i>Additive composition</i> Pentano-1,4-lactone <i>Characterisation of the active substance</i> Pentano-1,4-lactone Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₅ H ₈ O ₂ CAS number 108-29-2 FLAVIS No 10.013 <i>Method of analysis (1)</i> For the determination of pentano-1,4-lactone 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b10014	—	Nonano-1,5-lactone	<i>Additive composition</i> Nonano-1,5-lactone <i>Characterisation of the active substance</i> Nonano-1,5-lactone Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₉ H ₁₆ O ₂ CAS number 3301-94-8 FLAVIS No 10.014 <i>Method of analysis</i> ⁽¹⁾ For the determination of nonano-1,5-lactone 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b10015	—	Octano-1,5-lactone	<i>Additive composition</i> Octano-1,5-lactone <i>Characterisation of the active substance</i> Octano-1,5-lactone Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₁₄ O ₂ CAS number 698-76-0 FLAVIS No 10.015 <i>Method of analysis</i> ⁽¹⁾ For the determination of octano-1,5-lactone 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b10020	—	Heptano-1,4-lactone	<i>Additive composition</i> Heptano-1,4-lactone <i>Characterisation of the active substance</i> Heptano-1,4-lactone Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₇ H ₁₂ O ₂ CAS number 105-21-5 FLAVIS No 10.020 <i>Method of analysis</i> ⁽¹⁾ For the determination of heptano-1,4-lactone 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b10021	—	Hexano-1,4-lactone	<i>Additive composition</i> Hexano-1,4-lactone <i>Characterisation of the active substance</i> Hexano-1,4-lactone Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₆ H ₁₀ O ₂ CAS number 695-06-7 FLAVIS No 10.021 <i>Method of analysis</i> ⁽¹⁾ For the determination of hexano-1,4-lactone 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 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) 2017/57**of 14 December 2016****concerning the authorisation of 1,8-cineole, 3,4-dihydrocoumarin and 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran 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) 1,8-Cineole, 3,4-dihydrocoumarin and 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran were authorised without a time limit in accordance with 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 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 6 March 2012 and 13 November 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 further concluded that the function of 1,8-cineole, 3,4-dihydrocoumarin and 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran in feed is similar to that on food. The Authority has already concluded that for food those substances are efficacious, as they increase the food smell or palatability. Therefore, that conclusion can be extrapolated for feed. As the use of 1,8-cineole, 3,4-dihydrocoumarin and 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran in water for drinking is difficult to control when used simultaneously with feed, such use should be excluded. However, those substances 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, compound feeds and feed materials.
- (6) The Authority concluded that 1,8-cineole, 3,4-dihydrocoumarin and 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran are irritant to eyes, respiratory tract and skin. The Authority further concluded that 3,4-dihydrocoumarin is also skin sensitiser and harmful if swallowed. 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 2012;10(3):2622 and EFSA Journal 2012;10(11):2967

- (7) The assessment of 1,8-cineole, 3,4-dihydrocoumarin and 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran 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 1,8-cineole, 3,4-dihydrocoumarin and 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran 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 as specified in the Annex and premixtures containing those substances, which are produced and labelled before 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b03001	—	1,8-Cineole	<i>Additive composition</i> 1,8-Cineole <i>Characterisation of the active substance</i> 1,8-Cineole Produced by distillation from <i>Eucalyptus globulus</i> Purity: min. 98 % Chemical formula: $C_{10}H_{18}O$ CAS number 470-82-6 FLAVIS No 03.001 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1,8-cineole 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 shall be: 5 mg/kg of complete feedingstuff with a moisture content of 12 %. - 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’. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							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.	
2b13009	—	3,4-Dihydrocoumarin	<i>Additive composition</i> 3,4-Dihydrocoumarin <i>Characterisation of the active substance</i> 3,4-Dihydrocoumarin Produced by chemical synthesis Purity: min. 99 % Chemical formula: $C_9H_8O_2$ CAS number 119-84-6 FLAVIS No 13.009 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3,4-dihydrocoumarin 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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.	
2b13037	—	2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran	<i>Additive composition</i> 2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran <i>Characterisation of the active substance</i> 2-(2-Methylprop-1-enyl)-4-methyltetrahydropyran Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₁₀ H ₁₈ O CAS number 16409-43-1 FLAVIS No 13.037 <i>Method of analysis</i> ⁽¹⁾ For the identification of 2-(2-methylprop-1-enyl)-4-methyltetrahydropyran 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 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: For pigs and poultry: 0,5 mg/kg, and for other species and categories: 0,3 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 for pigs and poultry; — 0,3 mg/kg for other species and categories.'	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following contents of the active substance in complete feedingstuff with a moisture content of 12 % are exceeded: — 0,5 mg/kg for pigs and poultry; — 0,3 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) 2017/58**of 14 December 2016****concerning the authorisation of alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl 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) Alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl acetate were authorised without a time limit in accordance with 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 alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl acetate as feed additives 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 opinion of 13 November 2012 ⁽³⁾ that, under the proposed conditions of use in feed of alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl acetate do not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl acetate in feed is similar to that on food. The Authority has already concluded that for food alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl acetate are efficacious, as it increases the food smell or palatability. The Authority concluded that for nerolidol and 2-(4-methylphenyl) propan-2-ol the absence of margin of safety would not allow simultaneous administration in feed and water. For alpha-terpineol, terpineol and linalyl acetate the exact ratio for the inclusion in feed and water is not available. However, those substances can be used within a compound feed subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. For practical reasons and taking into account the re-evaluation performed by the Authority, maximum recommended contents should be set up. Where the recommended content of the additive in complete feedingstuff is exceeded, the identification number of the feed additive, its name and added amount should be indicated on the label of premixtures, compound feeds and feed materials.
- (6) The Authority concluded that in the absence of data on user safety alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl acetate should be considered as irritant to skin, eyes and respiratory tract and as a skin sensitizer. 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 2012;10(11):2966.

- (7) The assessment of alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl acetate 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 alpha-terpineol, nerolidol, 2-(4-methylphenyl) propan-2-ol, terpineol and linalyl acetate 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 as specified in the Annex and premixtures containing those substances, which are produced and labelled before 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identifica- tion number of the additive	Name of the holder of authoris- ation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authoris- ation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b02014	—	alpha-Terpineol	<i>Additive composition</i> alpha-Terpineol <i>Characterisation of the active substance</i> alpha-Terpineol Produced by chemical synthesis Purity: min. 96 % Chemical formula: C₁₀H₁₈O CAS No 98-55-5 FLAVIS No: 02.014 <i>Method of analysis</i> ⁽¹⁾ For the determination of alpha-Terpineol 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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.	
2b02018	—	Nerolidol	<i>Additive composition</i> Nerolidol <i>Characterisation of the active substance</i> Nerolidol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₅ H ₂₆ O CAS No 7212-44-4 FLAVIS No: 02.018 <i>Method of analysis</i> ⁽¹⁾ For the identification of Nerolidol 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: for pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 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 %: — 1 mg/kg for pigs and poultry; — 1,5 mg/kg for other species and categories.'	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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.	
2b02042	—	2-(4-Methylphenyl)propan-2-ol	Additive composition 2-(4-Methylphenyl)propan-2-ol Characterisation of the active substance 2-(4-Methylphenyl)propan-2-ol Produced by chemical synthesis Purity: min. 90 %	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: for pigs and poultry: 1 mg/kg, and for all other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: C₁₀H₁₄O CAS No 1197-01-9 FLAVIS No: 02.042 <i>Method of analysis</i> ⁽¹⁾ For the identification of 2-(4-Methylphenyl)propan-2-ol in the feed additive and 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 pigs and poultry; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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.	
2b02230	—	Terpineol	<i>Additive composition</i> Terpineol	All animal species	—	—	1. The additive shall be incorporated into the feed in the form of a premixture.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			<i>Characterisation of the active substance</i> Terpineol Produced by chemical synthesis Purity: min. 91 % Chemical formula: C₁₀H₁₈O CAS No 8000-41-7 FLAVIS No: 02.230 <i>Method of analysis</i> ⁽¹⁾ For the determination of Terpineol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.				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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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.	
2b09013	—	Linalyl acetate	<i>Additive composition</i> Linalyl acetate	All animal species	—	—	1. The additive shall be incorporated into the feed in the form of a premixture.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			<i>Characterisation of the active substance</i> Linalyl acetate Produced by chemical synthesis Purity: min. 95 % Chemical formula: $C_{12}H_{20}O_2$ CAS No 115-95-7 FLAVIS No: 09.013 <i>Method of analysis ⁽¹⁾</i> For the determination of Linalyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.				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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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) 2017/59**of 14 December 2016****concerning the authorisation of 1,1-dimethoxy-2-phenylethane, phenethyl formate, phenethyl octanoate, phenethyl isobutyrate, phenethyl 2-methyl-butyrate and phenethyl benzoate 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) 1,1-Dimethoxy-2-phenylethane, phenethyl formate, phenethyl octanoate, phenethyl isobutyrate, phenethyl 2-methyl-butyrate and phenethyl benzoate ('the substances concerned') were authorised without a time limit in accordance with 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 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 7 March 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 further concluded that the function of the substances concerned in feed is similar to that on food. The Authority has already concluded that for food those substances are efficacious, as they increase the food smell or palatability. Therefore, that conclusion can be extrapolated for feed. As the use of the substances concerned in water for drinking is difficult to control when used simultaneously with feed such use should be excluded. However, those substances 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, compound feeds and feed materials.
- (6) The Authority concluded that the substances concerned are considered as irritant to eyes and respiratory tract, skin sensitisers and harmful if swallowed. 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 feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2012;10(3):2625.

- (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 as specified in the Annex and premixtures containing those substances, which are produced and labelled before 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b06006	—	1,1-Dimethoxy-2-phenylethane	<i>Additive composition</i> 1,1-Dimethoxy-2-phenylethane <i>Characterisation of the active substance</i> 1,1-Dimethoxy-2-phenylethane Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₁₀H₁₄O₂ CAS number 101-48-4 FLAVIS No 06.006 <i>Method of analysis ⁽¹⁾</i> For the identification of 1,1-dimethoxy-2-phenylethane in the feed additive and 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 shall be: For pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %. - 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; — 1,5 mg/kg for other species and categories.'	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following contents of the active substance in complete feedingstuff with a moisture content of 12 % are exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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.	
2b09083	—	Phenethyl formate	<i>Additive composition</i> Phenethyl formate <i>Characterisation of the active substance</i> Phenethyl formate Produced by chemical synthesis Purity: min. 96 % Chemical formula: C₉H₁₀O₂ CAS number 104-62-1 FLAVIS No 09.083	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: For pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			<i>Method of analysis</i> ⁽¹⁾ For the identification of phenethyl formate in the feed additive and 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 pigs and poultry; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following contents of the active substance in complete feedingstuff with a moisture content of 12 % are exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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.	
2b09262	—	Phenethyl octanoate	<i>Additive composition</i> Phenethyl octanoate <i>Characterisation of the active substance</i> Phenethyl octanoate	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.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₁₆H₂₄O₂ CAS number 5457-70-5 FLAVIS No 09.262 <i>Method of analysis</i> ⁽¹⁾ For the identification of phenethyl octanoate in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.				3. The recommended maximum content of the active substance shall be: For pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 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 %: — 1 mg/kg for pigs and poultry; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following contents of the active substance in complete feedingstuff with a moisture content of 12 % are exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b09427	—	Phenethyl isobutyrate	<i>Additive composition</i> Phenethyl isobutyrate <i>Characterisation of the active substance</i> Phenethyl isobutyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₁₂H₁₆O₂ CAS number 103-48-0 FLAVIS No 09.427 <i>Method of analysis</i> ⁽¹⁾ For the identification of phenethyl isobutyrate 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: For pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 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 %: — 1 mg/kg for pigs and poultry; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following contents of the active substance in complete feedingstuff with a moisture content of 12 % are exceeded: — 1 mg/kg for pigs and poultry; — 1,5 mg/kg for other species and categories.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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.	
2b09538	—	Phenethyl 2-methyl-butyrate	<i>Additive composition</i> Phenethyl 2-methyl-butyrate <i>Characterisation of the active substance</i> Phenethyl 2-methyl-butyrate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₁₃H₁₈O₂ CAS number 24817-51-4 FLAVIS No 09.538 <i>Method of analysis (1)</i> For the identification of phenethyl 2-methyl-butyrate 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: For pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 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 %: — 1 mg/kg for pigs and poultry; — 1,5 mg/kg for other species and categories.’	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following contents of the active substance in complete feedingstuff with a moisture content of 12 % are exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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..	
2b09774	—	Phenethyl benzoate	<i>Additive composition</i> Phenethyl benzoate <i>Characterisation of the active substance</i> Phenethyl benzoate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₁₅H₁₄O₂ CAS number 94-47-3 FLAVIS No 09.774	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: For pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			<i>Method of analysis</i> ⁽¹⁾ For the identification of phenethyl benzoate in the feed additive and 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 pigs and poultry; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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) 2017/60**of 14 December 2016****concerning the authorisation of isoeugenol as a feed additive for pigs, ruminants and horses except those producing milk for human consumption and pets****(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) Isoeugenol, was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That product was 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 isoeugenol as a feed additive for all animal species except for poultry, ruminants producing milk for human consumption and fish. The applicant requested that additive 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 14 December 2011 ⁽³⁾ that, under the proposed conditions of use in feed, isoeugenol does not have adverse effects on animal health, human health or the environment. Isoeugenol should not be allowed for those categories of mammal species intended for the production of milk for human consumption. The Authority further concluded that the function of isoeugenol in feed is similar to that on food. The Authority has already concluded that for food isoeugenol is efficacious, as it increases the food smell or palatability. Therefore, that conclusion can be extrapolated for feed. The Authority concluded that the simultaneous use in feed and water for drinking should be avoided. However, those substances 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, compound feeds and feed materials.
- (6) The Authority concluded that isoeugenol is an irritant to the respiratory tract, skin and eyes and it is also a skin and respiratory sensitiser. 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.
- (7) The assessment of the substance 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 that substance 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 2012;10(1):2532.

- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for that substance 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 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 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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

2b04004	—	Isoeugenol	<i>Additive composition</i> Isoeugenol <i>Characterisation of the active substance</i> Isoeugenol Produced by chemical synthesis Purity: min. 99 % Chemical formula: $C_{10}H_{12}O_2$ CAS number 97-54-1 FLAVIS No 04.004 <i>Method of analysis (1)</i> For the identification of isoeugenol in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	Pigs Ruminants and horses except those producing milk for human consumption Pets	—	—	—	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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027
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								6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
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(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) 2017/61**of 14 December 2016****concerning the authorisation of 4-allyl-2,6-dimethoxyphenol and eugenyl acetate as feed additives for all animal species except for fish and poultry****(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) 4-Allyl-2,6-dimethoxyphenol and eugenyl acetate were authorised without a time limit in accordance with Directive 70/524/EEC as feeds 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. 4-Allyl-2,6-dimethoxyphenol and eugenyl acetate for poultry and fish will not be re-authorised as they were withdrawn by the applicant.
- (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 4-allyl-2,6-dimethoxyphenol and eugenyl acetate as feed additives 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 opinion of 15 November 2011 ⁽³⁾ that, under the proposed conditions of use in feed, 4-allyl-2,6-dimethoxyphenol and eugenyl acetate do not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of 4-allyl-2,6-dimethoxyphenol and eugenyl acetate in feed is similar to that on food. The Authority has already concluded that for food those substances are efficacious, as it increases the food smell or palatability. Therefore, that conclusion can be extrapolated for feed. The Authority is not in a position to evaluate the use 4-allyl-2,6-dimethoxyphenol and eugenyl acetate in water for drinking. However, those substances 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, compound feeds and feed materials.
- (6) The Authority concluded that 4-allyl-2,6-dimethoxyphenol is irritant to eyes and skin and that eugenyl acetate is irritant to skin only. 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 4-allyl-2,6-dimethoxyphenol and eugenyl acetate 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 feeding-stuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2011;9(12):2440.

- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for 4-allyl-2,6-dimethoxyphenol and eugenyl acetate, 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 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b04051	—	4-Allyl-2,6-dimethoxyphenol	<i>Additive composition</i> 4-Allyl-2,6-dimethoxyphenol <i>Characterisation of the active substance</i> 4-Allyl-2,6-dimethoxyphenol Produced by chemical synthesis Purity: min. 98 % Chemical formula: $C_{11}H_{14}O_3$ CAS number 6627-88-9 FLAVIS No 04.051 <i>Method of analysis</i> ⁽¹⁾ For the identification of 4-allyl-2,6-dimethoxyphenol in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species except fish and poultry)	—	—	—	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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09020	—	Eugenyl acetate	<i>Additive composition</i> Eugenyl acetate <i>Characterisation of the active substance</i> Eugenyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₂ H ₁₄ O ₃ CAS number 93-28-7 FLAVIS No 09.020 <i>Method of analysis</i> ⁽¹⁾ For the identification of eugenyl acetate in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species except fish and poultry.	—	—	—	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'.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 dermal contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including 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) 2017/62

of 14 December 2016

concerning the authorisation of 3-(methylthio) propionaldehyde, methyl 3-(methylthio) propionate, allylthiol, dimethyl sulfide, dibutyl sulfide, diallyl disulfide, diallyl trisulfide, dimethyl trisulfide, dipropyl disulfide, allyl isothiocyanate, dimethyl disulfide, 2-methylbenzene-1-thiol, S-methyl butanethioate, allyl methyl disulfide, 3-(methylthio) propan-1-ol, 3-(methylthio) hexan-1-ol, 1-propane-1-thiol, diallyl sulfide, 2,4-dithiapentane, 2-methyl-2-(methyldithio) propanal, 2-methylpropane-1-thiol, methylsulfinyl methane, propane-2-thiol, 3,5-dimethyl-1,2,4-trithiolane and 2-methyl-4-propyl-1,3-oxathiane 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) 3-(Methylthio) propionaldehyde, methyl 3-(methylthio) propionate, allylthiol, dimethyl sulfide, dibutyl sulfide, diallyl disulfide, diallyl trisulfide, dimethyl trisulfide, dipropyl disulfide, allyl isothiocyanate, dimethyl disulfide, 2-methylbenzene-1-thiol, S-methyl butanethioate, allyl methyl disulfide, 3-(methylthio) propan-1-ol, 3-(methylthio) hexan-1-ol, 1-propane-1-thiol, diallyl sulfide, 2,4-dithiapentane, 2-methyl-2-(methyldithio) propanal, 2-methylpropane-1-thiol, methylsulfinyl methane, propane-2-thiol, 3,5-dimethyl-1,2,4-trithiolane and 2-methyl-4-propyl-1,3-oxathiane ('the substances concerned') were authorised without a time limit in accordance with 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 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 17 April 2013 ⁽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. For allyl isothiocyanate, the Authority stated that, although additional exposure to that substance through its low use level in animal feeds would not substantially increase consumer exposure, the estimated exposure of consumers is already higher than the acceptable daily intake. For allyl isothiocyanate and 2-methylpropane-1-thiol maximum contents should be set up to ensure consumer safety and environmental protection, respectively. The Authority further concluded that the function of the substances concerned in feed is similar to that on food. The Authority has already concluded that for food the substances concerned are efficacious, as it increases the food smell or palatability. Therefore, that conclusion can be extrapolated for feed. The Authority could not conclude on the safety of the substances concerned used in water for drinking. However, those substances can be used within compound feeds which are subsequently administered via water.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ EFSA Journal 2013;11(5):3208.

- (5) Restrictions and conditions should be provided for to allow better control. For all the substances except allyl isothiocyanate and 2-methylpropane-1-thiol, 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, compound feeds and feed materials.
- (6) The Authority concluded that the substances concerned are to be considered as being irritant to skin, eyes and respiratory tract and as a skin sensitiser. 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 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

*Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b12001	—	3-(Methylthio) propionaldehyde	<i>Additive composition</i> 3-(Methylthio) propionaldehyde <i>Characterisation of the active substance</i> 3-(Methylthio) propionaldehyde Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₄H₈OS CAS number 3268-49-3 FLAVIS No 12.001 <i>Method of analysis (1)</i> For the determination of 3-(methylthio) propionaldehyde 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 shall be: 0,05 mg/kg of complete feedingstuff with a moisture content of 12 %. - 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'. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12002	—	Methyl 3-(methylthio)propionate	<i>Additive composition</i> Methyl 3-(methylthio)propionate <i>Characterisation of the active substance</i> Methyl 3-(methylthio)propionate Produced by chemical synthesis Purity: min. 97 % Chemical formula: $C_5H_{10}O_2S$ CAS number 13532-18-8 FLAVIS No 12.002 <i>Method of analysis (1)</i> For the determination of methyl 3-(methylthio)propionate 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12004	—	Allylthiol	<i>Additive composition</i> Allylthiol <i>Characterisation of the active substance</i> Allylthiol Produced by chemical synthesis Purity: min. 75 % (min. 98 % allylthiol + allyl sulphide + allyl mercaptan) Chemical formula: C ₃ H ₆ S CAS number 870-23-5 FLAVIS No 12.004 <i>Method of analysis</i> ⁽¹⁾ For the determination of allylthiol 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12006	—	Dimethyl sulfide	<i>Additive composition</i> Dimethyl sulfide <i>Characterisation of the active substance</i> Dimethyl sulfide Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₂H₆S CAS number 75-18-3 FLAVIS No 12.006 <i>Method of analysis</i> ⁽¹⁾ For the determination of dimethyl 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. The recommended maximum content of the active substance shall be: 0,05 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 %: 0,05 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12007	—	Dibutyl sulfide	<i>Additive composition</i> Dibutyl sulfide <i>Characterisation of the active substance</i> Dibutyl sulfide Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₈H₁₈S CAS number 544-40-1 FLAVIS No 12.007 <i>Method of analysis</i> ⁽¹⁾ For the determination of dibutyl 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. The recommended maximum content of the active substance shall be: 0,05 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 %: 0,05 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12008	—	Diallyl disulfide	<i>Additive composition</i> Diallyl disulfide <i>Characterisation of the active substance</i> Diallyl disulfide Produced by chemical synthesis Purity: min. 80 % (min. 98 % diallyl disulphide + allyl sulphide + allyl mercaptan) Chemical formula: C ₆ H ₁₀ S ₂ CAS number 2179-57-9 FLAVIS No 12.008 <i>Method of analysis</i> ⁽¹⁾ For the determination of diallyl 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 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12009	—	Diallyl trisulfide	<i>Additive composition</i> Diallyl trisulfide <i>Characterisation of the active substance</i> Diallyl trisulfide Produced by chemical synthesis Purity: min. 65 % (min.95 % allyl di-, tri- and tetra sulfides) Chemical formula: C ₆ H ₁₀ S ₃ CAS number 2050-87-5 FLAVIS No 12.009 <i>Method of analysis</i> ⁽¹⁾ For the determination of diallyl trisulfide 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12013	—	Dimethyl trisulfide	<i>Additive composition</i> Dimethyl trisulfide <i>Characterisation of the active substance</i> Dimethyl trisulfide Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₂H₆S₃ CAS number 3658-80-8 FLAVIS No 12.013 <i>Method of analysis</i> ⁽¹⁾ For the determination of dimethyl trisulfide 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: 0,05 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 %: 0,05 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12014	—	Dipropyl disulfide	<i>Additive composition</i> Dipropyl disulfide <i>Characterisation of the active substance</i> Dipropyl disulfide Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₆ H ₁₄ S ₂ CAS number 629-19-6 FLAVIS No 12.014 <i>Method of analysis</i> (1) For the determination of dipropyl 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 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b12025	—	Allyl isothiocyanate	<i>Additive composition</i> Allyl isothiocyanate <i>Characterisation of the active substance</i> Allyl isothiocyanate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C_4H_5NS CAS number 57-06-7 FLAVIS No 12.025 <i>Method of analysis</i> ⁽¹⁾ For the identification of allyl isothiocyanate in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	0,05	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. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12026	—	Dimethyl disulfide	<i>Additive composition</i> Dimethyl disulfide <i>Characterisation of the active substance</i> Dimethyl disulfide Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₂H₆S₂ CAS number 624-92-0 FLAVIS No 12.026 <i>Method of analysis ⁽¹⁾</i> For the determination of dimethyl 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. The recommended maximum content of the active substance shall be: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12027	—	2-Methylbenzene-1-thiol	<i>Additive composition</i> 2-Methylbenzene-1-thiol <i>Characterisation of the active substance</i> 2-Methylbenzene-1-thiol Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₇H₈S CAS number 137-06-4 FLAVIS No 12.027 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2-methylbenzene-1-thiol 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12032	—	S-Methyl butanethioate	<i>Additive composition</i> S-Methyl butanethioate <i>Characterisation of the active substance</i> S-Methyl butanethioate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₅H₁₀OS CAS number 2432-51-1 FLAVIS No 12.032 <i>Method of analysis</i> ⁽¹⁾ For the determination of S-methyl butanethioate 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: 0,05 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 %: 0,05 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12037	—	Allyl methyl disulfide	<i>Additive composition</i> Allyl methyl disulfide <i>Characterisation of the active substance</i> Allyl methyl disulfide Produced by chemical synthesis Purity: min. 90 % Chemical formula: C₄H₈S₂ CAS number 2179-58-0 FLAVIS No 12.037 <i>Method of analysis</i> ⁽¹⁾ For the determination of allyl methyl 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. The recommended maximum content of the active substance shall be: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12062	—	3-(Methylthio)propan-1-ol	<i>Additive composition</i> 3-(Methylthio)propan-1-ol <i>Characterisation of the active substance</i> 3-(Methylthio)propan-1-ol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₄H₁₀OS CAS number 505-10-2 FLAVIS No 12.062 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3-(methylthio)propan-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: 0,05 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 %: 0,05 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12063	—	3-(Methylthio)hexan-1-ol	<i>Additive composition</i> 3-(Methylthio)hexan-1-ol <i>Characterisation of the active substance</i> 3-(Methylthio)hexan-1-ol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₇H₁₆OS CAS number 51755-66-9 FLAVIS No 12.063 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3-(methylthio)hexan-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	—	—	—	- 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 shall be: 0,05 mg/kg of complete feedingstuff with a moisture content of 12 %. - 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'. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 0,05 mg/kg. - For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12071	—	1-Propane-1-thiol	<i>Additive composition</i> 1-Propane-1-thiol <i>Characterisation of the active substance</i> 1-Propane-1-thiol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₃H₈S CAS number 107-03-9 FLAVIS No 12.071 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1-propane-1-thiol 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12088	—	Diallyl sulfide	<i>Additive composition</i> Diallyl sulfide <i>Characterisation of the active substance</i> Diallyl sulfide Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₆H₁₀S CAS number 592-88-1 FLAVIS No 12.088 <i>Method of analysis</i> ⁽¹⁾ For the determination of diallyl 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. The recommended maximum content of the active substance shall be: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12118	—	2,4-Dithiapentane	<i>Additive composition</i> 2,4-Dithiapentane <i>Characterisation of the active substance</i> 2,4-Dithiapentane Produced by chemical synthesis Purity: min. 99 % Chemical formula: C₃H₈S₂ CAS number 1618-26-4 FLAVIS No 12.118 <i>Method of analysis</i> ⁽¹⁾ For the determination of 2,4-dithiapentane 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12168	—	2-Methyl-2-(methylthio)propanal	<i>Additive composition</i> 2-Methyl-2-(methylthio)propanal <i>Characterisation of the active substance</i> 2-Methyl-2-(methylthio)propanal Produced by chemical synthesis Purity: min. 95 % Chemical formula: $C_5H_{10}OS_2$ CAS number 67952-60-7 FLAVIS No 12.168 <i>Method of analysis ⁽¹⁾</i> For the determination of 2-methyl-2-(methylthio)propanal 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: 0,05 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 %: 0,05 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b12173	—	2-Methylpropane-1-thiol	<i>Additive composition</i> 2-Methylpropane-1-thiol <i>Characterisation of the active substance</i> 2-Methylpropane-1-thiol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₄H₁₀S CAS number 513-44-0 FLAVIS No 12.173 <i>Method of analysis ⁽¹⁾</i> For the identification of 2-methylpropane-1-thiol in the feed additive and flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	—	—	0,04	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. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	6 February 2027
2b12175	—	Methylsulfinyl methane	<i>Additive composition</i> Methylsulfinylmethane <i>Characterisation of the active substance</i> Methylsulfinylmethane Produced by chemical synthesis Purity: min. 99 % Chemical formula: C₂H₆OS CAS number 67-68-5 FLAVIS No 12.175	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: 0,05 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			<i>Method of analysis</i> ⁽¹⁾ For the determination of methylsulfinylmethane 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b12197	—	Propane-2-thiol	<i>Additive composition</i> Propane-2-thiol <i>Characterisation of the active substance</i> Propane-2-thiol 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.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: C ₃ H ₈ S CAS number 75-33-2 FLAVIS No 12.197 <i>Method of analysis</i> ⁽¹⁾ For the determination of propane-2-thiol 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: 0,05 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 %: 0,05 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b15025	—	3,5-Dimethyl-1,2,4-trithiolane	<i>Additive composition</i> 3,5-Dimethyl-1,2,4-trithiolane	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.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			<i>Characterisation of the active substance</i> 3,5-Dimethyl-1,2,4-trithiolane Produced by chemical synthesis Purity: min. 90 % Secondary components: diethyl trisulphide, dimethylbenzylcarbinol, N, N-dimethyl-ethanethioamide, 4,6-dimethyl-1,2,3,5-tetracyclohexane, 3-methyl-1,2,4-trithiolane, 2-methyl-4-propyl 1,3-oxathiane Chemical formula: C₄H₈S₃ CAS number 23654-92-4 FLAVIS No 15.025 <i>Method of analysis</i> ⁽¹⁾ For the determination of 3,5-dimethyl-1,2,4-trithiolane 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b16030	—	2-Methyl-4-propyl-1,3-oxathiane	<i>Additive composition</i> 2-Methyl-4-propyl-1,3-oxathiane	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.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			<i>Characterisation of the active substance</i> 2-Methyl-4-propyl-1,3-oxathiane Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₈H₁₆OS CAS number 67715-80-4 FLAVIS No 16.030 <i>Method of analysis ⁽¹⁾</i> For the determination of 2-methyl-4-propyl-1,3-oxathiane 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: 0,05 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 %: 0,05 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 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) 2017/63
of 14 December 2016

concerning the authorisation of benzyl alcohol, 4-isopropylbenzyl alcohol, benzaldehyde, 4-isopropylbenzaldehyde, salicylaldehyde, p-tolualdehyde, 2-methoxybenzaldehyde, benzoic acid, benzyl acetate, benzyl butyrate, benzyl formate, benzyl propionate, benzyl hexanoate, benzyl isobutyrate, benzyl isovalerate, hexyl salicylate, benzyl phenylacetate, methyl benzoate, ethyl benzoate, isopentyl benzoate, pentyl salicylate and isobutyl benzoate as feed additives for all animal species and of veratraldehyde and gallic acid as feed additives for certain 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) Benzyl alcohol, 4-isopropylbenzyl alcohol, benzaldehyde, veratraldehyde, 4-isopropylbenzaldehyde, salicylaldehyde, p-tolualdehyde, 2-methoxybenzaldehyde, benzoic acid, gallic acid, benzyl acetate, benzyl butyrate, benzyl formate, benzyl propionate, benzyl hexanoate, benzyl isobutyrate, benzyl isovalerate, hexyl salicylate, benzyl phenylacetate, methyl benzoate, ethyl benzoate, isopentyl benzoate, pentyl salicylate and isobutyl benzoate ('substances concerned') were authorised without a time limit in accordance with 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. Veratraldehyde for poultry and fish and gallic acid for fish will not be re-authorised as they were withdrawn by the applicant.
- (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 benzyl alcohol, 4-isopropylbenzyl alcohol, benzaldehyde, 4-isopropylbenzaldehyde, salicylaldehyde, p-tolualdehyde, 2-methoxybenzaldehyde, benzoic acid, benzyl acetate, benzyl butyrate, benzyl formate, benzyl propionate, benzyl hexanoate, benzyl isobutyrate, benzyl isovalerate, hexyl salicylate, benzyl phenylacetate, methyl benzoate, ethyl benzoate, isopentyl benzoate, pentyl salicylate and isobutyl benzoate as feed additives for all animal species and of veratraldehyde and gallic acid as feed additives for certain 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 13 June 2012 ⁽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 on 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 Authority cannot conclude on the safety of the concerned substances in water for drinking. However, those substances can be used within compound feeds which are subsequently administered via water.

⁽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):2785.

- (5) Restrictions and conditions should be provided for to allow better control. Since safety reasons do not require the setting of a maximum content, except for benzoic acid, 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, compound feeds and feed materials.
- (6) The Authority concluded that in the absence of data the substances concerned should be considered as potentially hazardous to the respiratory tract, skin and eyes, skin sensitisers and harmful if swallowed. 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 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

*Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b02010	—	Benzyl alcohol	<i>Additive composition</i> Benzyl alcohol <i>Characterisation of the active substance</i> Benzyl alcohol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₇H₈O CAS number 100-51-6 FLAVIS No 02.010 <i>Method of analysis</i> ⁽¹⁾ For the determination of benzyl alcohol 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 shall be: 125 mg/kg of complete feedingstuff with a moisture content of 12 %. - 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 %: 125 mg/kg'. - The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 125 mg/kg.	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b02039	—	4-Isopropylbenzyl alcohol	<i>Additive composition</i> 4-Isopropylbenzyl alcohol <i>Characterisation of the active substance</i> 4-Isopropylbenzyl alcohol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₀ H ₁₄ O CAS number 536-60-7 FLAVIS No 02.039 <i>Method of analysis</i> (1) For the determination of 4-isopropylbenzyl 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 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b05013	—	Benzaldehyde	<i>Additive composition</i> Benzaldehyde <i>Characterisation of the active substance</i> Benzaldehyde Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₇H₆O CAS number 100-52-7 FLAVIS No 05.013 <i>Method of analysis ⁽¹⁾</i> For the determination of benzaldehyde 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: 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’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b05017	—	Veratraldehyde	<i>Additive composition</i> Veratraldehyde <i>Characterisation of the active substance</i> Veratraldehyde Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₉ H ₁₀ O ₃ CAS number 120-14-9 FLAVIS No 05.017 <i>Method of analysis</i> ⁽¹⁾ For the identification of veratraldehyde in the feed additive and flavouring pre-mixtures. Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species except poultry and fish	—	—	—	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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b05022	—	4-Isopropylbenzaldehyde	<i>Additive composition</i> 4-Isopropylbenzaldehyde <i>Characterisation of the active substance</i> 4-Isopropylbenzaldehyde Produced by chemical synthesis Purity: min. 95 % Chemical formula: C₁₀H₁₂O CAS number 122-03-2 FLAVIS No 05.022 <i>Method of analysis</i> ⁽¹⁾ For the determination of 4-isopropylbenzaldehyde 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b05055	—	Salicylaldehyde	<i>Additive composition</i> Salicylaldehyde <i>Characterisation of the active substance</i> Salicylaldehyde Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₇ H ₆ O ₂ CAS number 90-02-8 FLAVIS No 05.055 <i>Method of analysis</i> ⁽¹⁾ For the identification of salicylaldehyde 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 1 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b05029	—	p-Tolualdehyde	<i>Additive composition</i> p-Tolualdehyde <i>Characterisation of the active substance</i> p-Tolualdehyde Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₈H₈O CAS number 104-87-0 FLAVIS No 05.029 <i>Method of analysis ⁽¹⁾</i> For the determination of p-tolualdehyde 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b05129	—	2-Methoxybenzaldehyde	<i>Additive composition</i> 2-Methoxybenzaldehyde <i>Characterisation of the active substance</i> 2-Methoxybenzaldehyde Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₈ H ₈ O ₂ CAS number 135-02-4 FLAVIS No 05.129 <i>Method of analysis</i> ⁽¹⁾ For the identification of 2-methoxybenzaldehyde 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 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’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 1 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b08021	—	Benzoic acid	<i>Additive composition</i> Benzoic acid <i>Characterisation of the active substance</i> Benzenecarboxylic acid, phenylcarboxylic acid Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₇ H ₆ O ₂ CAS number 65-85-0 FLAVIS No 08.021 Maximum level of impurities Phthalic acid: ≤ 100 mg/kg; Biphenyl: ≤ 100 mg/kg	All animal species	—	—	125	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. For users of the additive and pre-mixtures in a feed business, operational procedures and appropriate organisational measures shall be established to address hazards by inhalation, dermal contact or eyes contact. Where the dermal, inhalatory or eyes exposure cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			<i>Method of analysis</i> ⁽¹⁾ For the determination of benzoic acid in the feed additive and in feed flavouring premixtures. Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.						
2b08080	—	Gallic acid	<i>Additive composition</i> Gallic acid <i>Characterisation of the active substance</i> Gallic acid Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₇ H ₆ O ₅ CAS number 149-91-7 FLAVIS No 08.080 <i>Method of analysis</i> ⁽¹⁾ For the identification of gallic acid in the feed additive and 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. 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'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09014	—	Benzyl acetate	<i>Additive composition</i> Benzyl acetate <i>Characterisation of the active substance</i> Benzyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₉H₁₀O₂ CAS number 140-11-4 FLAVIS No 09.014 <i>Method of analysis ⁽¹⁾</i> For the determination of benzyl 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: 125 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 %: 125 mg/kg’. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 125 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09051	—	Benzyl butyrate	<i>Additive composition</i> Benzyl butyrate <i>Characterisation of the active substance</i> Benzyl butyrate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C₁₁H₁₄O₂ CAS number 103-37-7 FLAVIS No 09.051 <i>Method of analysis ⁽¹⁾</i> For the determination of benzyl butyrate 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09077	—	Benzyl formate	<i>Additive composition</i> Benzyl formate <i>Characterisation of the active substance</i> Benzyl formate Produced by chemical synthesis Purity: min. 95 % Chemical formula: C ₈ H ₈ O ₂ CAS number 104-57-4 FLAVIS No 09.077 <i>Method of analysis</i> ⁽¹⁾ For the determination of benzyl formate 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: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
							6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09132	—	Benzyl propionate	<i>Additive composition</i> Benzyl propionate <i>Characterisation of the active substance</i> Benzyl propionate Produced by chemical synthesis Purity: min. 98 % Chemical formula: $C_{10}H_{12}O_2$ CAS number 122-63-4 FLAVIS No 09.132 <i>Method of analysis ⁽¹⁾</i> For the determination of benzyl propionate 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: 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'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09316		Benzyl hexanoate	<i>Additive composition</i> Benzyl hexanoate <i>Characterisation of the active substance</i> Benzyl hexanoate Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₁₃ H ₁₈ O ₂ CAS number 6938-45-0 FLAVIS No 09.316 <i>Method of analysis</i> ⁽¹⁾ For the identification of benzyl hexanoate 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 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: for pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 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 %: — 1 mg/kg for pigs and poultry; — 1,5 mg/kg for other species and categories'.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 1 mg/kg for pigs and poultry; — 1,5 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 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 safety glasses and gloves.	
2b09426	—	Benzyl isobutyrate	Additive composition Benzyl isobutyrate Characterisation of the active substance Benzyl isobutyrate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₁₁H₁₄O₂	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 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			CAS number 103-28-6 FLAVIS No 09.426 <i>Method of analysis</i> ⁽¹⁾ For the determination of benzyl isobutyrate 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 %: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b09458	—	Benzyl isovalerate	<i>Additive composition</i> Benzyl isovalerate <i>Characterisation of the active substance</i> Benzyl isovalerate 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: 5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: $C_{12}H_{16}O_2$ CAS number 103-38-8 FLAVIS No 09.458 <i>Method of analysis</i> ⁽¹⁾ For the determination of benzyl isovalerate 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 %: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b09581	—	Hexyl salicylate	<i>Additive composition</i> Hexyl salicylate <i>Characterisation of the active substance</i> Hexyl salicylate Produced by chemical synthesis Purity: min. 99 %	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 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: $C_{13}H_{18}O_3$ CAS number 6259-76-3 FLAVIS No 09.581 <i>Method of analysis</i> ⁽¹⁾ For the identification of hexyl salicylate in the feed additive and 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b09705	—	Benzyl phenylacetate	<i>Additive composition</i> Benzyl phenylacetate <i>Characterisation of the active substance</i> Benzyl phenylacetate 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: 5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: $C_{15}H_{14}O_2$ CAS number 102-16-9 FLAVIS No 09.705 <i>Method of analysis</i> ⁽¹⁾ For the determination of benzyl phenylacetate 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 %: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b09725	—	Methyl benzoate	<i>Additive composition</i> Methyl benzoate <i>Characterisation of the active substance</i> Methyl benzoate 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: 5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: C ₈ H ₈ O ₂ CAS number 93-58-3 FLAVIS No 09.725 <i>Method of analysis</i> ⁽¹⁾ For the determination of methyl benzoate 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 %: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b09726	—	Ethyl benzoate	<i>Additive composition</i> Ethyl benzoate <i>Characterisation of the active substance</i> Ethyl benzoate 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: 5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			Chemical formula: C ₉ H ₁₀ O ₂ CAS number 93-89-0 FLAVIS No 09.726 <i>Method of analysis</i> ⁽¹⁾ For the determination of ethyl benzoate 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 %: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b09755	—	Isopentyl benzoate	<i>Additive composition</i> Isopentyl benzoate <i>Characterisation of the active substance</i> Isopentyl benzoate 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: 5 mg/kg of complete feedingstuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: $C_{12}H_{16}O_2$ CAS number 94-46-2 FLAVIS No 09.755 <i>Method of analysis</i> ⁽¹⁾ For the determination of isopentyl benzoate 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 %: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 safety glasses and gloves.	
2b09762	—	Pentyl salicylate	<i>Additive composition</i> Pentyl salicylate <i>Characterisation of the active substance</i> Pentyl salicylate Produced by chemical synthesis Purity: min. 95 %	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 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			Chemical formula C ₁₂ H ₁₆ O ₃ CAS number 2050-08-0 FLAVIS No 09.762 <i>Method of analysis</i> ⁽¹⁾ For the identification of pentyl salicylate in the feed additive and flavouring pre-mixtures. 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 labelling of the premixtures, feed materials and compound feeding-stuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 1 mg/kg. 6. For users of the additive and pre-mixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
2b09757	—	Isobutyl benzoate	<i>Additive composition</i> Isobutyl benzoate <i>Characterisation of the active substance</i> Isobutyl benzoate Produced by chemical synthesis Purity: min. 98 %	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: 5 mg/kg of complete feeding-stuff with a moisture content of 12 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			Chemical formula: $C_{11}H_{14}O_2$ CAS number 120-50-3 FLAVIS No 09.757 <i>Method of analysis</i> ⁽¹⁾ For the determination of isobutyl benzoate 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 %: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 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 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) 2017/64
of 14 December 2016
concerning the authorisation of glycyrrhizic acid ammoniated as a feed additive for all animal species
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Glycyrrhizic acid ammoniated was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That product was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (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 glycyrrhizic acid ammoniated as a feed additive for all animal species. The applicant requested that additive 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 11 December 2014 ⁽³⁾ that, under the proposed conditions of use in feed glycyrrhizic acid ammoniated does not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of glycyrrhizic acid ammoniated in feed is similar to that on food. The Authority has already concluded that for food glycyrrhizic acid ammoniated is efficacious, as it increases the food smell or palatability. The Authority could not conclude on the safety of for glycyrrhizic acid ammoniated used in water for drinking. However, that substance can be used within a compound feed subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. For practical reasons and taking into account the re-evaluation performed by the Authority, maximum recommended contents should be set up. Where the recommended content of the additive in complete feedingstuff is exceeded, the identification number of the feed additive, its name and added amount should be indicated on the label of premixtures, compound feeds and feed materials.
- (6) The Authority concluded that in the absence of data on user safety glycyrrhizic acid ammoniated should be considered as irritant to skin, eyes and respiratory tract and as a skin sensitiser. 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.
- (7) The assessment of glycyrrhizic acid ammoniated 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.

⁽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 2015;13(1):3971.

- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for glycyrrhizic acid ammoniated, 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 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 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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

2b16060	—	Glycyrrhizic acid ammoniated	<i>Additive composition</i> Glycyrrhizic acid ammoniated <i>Characterisation of the active substance</i> Glycyrrhizic acid ammoniated Produced by extraction of species of the genus Glycyrrhiza Purity: min. 98-100 % (on dry matter basis) Chemical formula: $C_{42}H_{65}O_{16}$ CAS No 53956-04-0 FLAVIS No: 16.060 <i>Method of analysis</i> ⁽¹⁾ For the identification of the glycyrrhizic acid ammoniated in the feed additive and flavouring premixtures: European Pharmacopoeian 6.0, method 01/2008:1772.	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 chickens for fattening and laying hens, — 1 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 0,3 mg/kg for chickens for fattening and laying hens,	6 February 2027
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								— 1 mg/kg for other species and categories. 5. 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.	
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(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) 2017/65

of 14 December 2016

concerning the authorisation of 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene 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) 1-Isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene, were authorised without a time limit in accordance with 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 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene as feed additives 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 ⁽³⁾ of 10 March 2015 and of 1 December 2015 that, under the proposed conditions of use in feed 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene do not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene in feed is similar to that on food. The Authority has already concluded that for food 1-isopropyl-4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene are efficacious, as it increases the food smell or palatability. The Authority could not conclude on the safety of for pin-2(3)-ene, pin-2(10)-ene, delta-3-carene, beta-caryophyllene and camphene used in water for drinking. The Authority concluded that for d-limonene, 1-isopropyl-4-methylbenzene and 1-isopropenyl-4-methylbenzene the absence of margin of safety would not allow simultaneous administration in feed and water. However, those substances can be used within a compound feed subsequently administered via water.
- (5) Restrictions and conditions should be provided for to allow better control. For practical reasons and taking into account the re-evaluation performed by the Authority, maximum recommended contents should be set up. Where the recommended content of the additive in complete feedingstuff is exceeded, the identification number of the feed additive, its name and added amount should be indicated on the label of premixtures, 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 2015;13(3):4053 and EFSA Journal 2016;14(1):4339

- (6) The Authority concluded that in the absence of data on user safety 1-Isopropyl- 4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene should be considered as irritant to skin, eyes and respiratory tract and as a skin sensitiser. 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 1-isopropyl- 4-methylbenzene, pin-2(10)-ene, pin-2(3)-ene, beta-caryophyllene, camphene, 1-isopropenyl-4-methylbenzene, delta-3-carene and d-limonene 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 as specified in the Annex and premixtures containing those substances, which are produced and labelled before 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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 %			
(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)

Category: Sensory additives. Functional group: Flavouring compounds

2b01002	—	1-Isopropyl-4-methylbenzene	<i>Additive composition</i> 1-Isopropyl-4-methylbenzene <i>Characterisation of the active substance</i> 1-Isopropyl-4-methylbenzene Produced by chemical synthesis Purity: min 97 % C₁₀H₁₄ CAS No 99-87-6 FLAVIS No: 01.002 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1-isopropyl-4-methylbenzene 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 shall be: For cats: 14 mg/kg, and for other species and categories: 25 mg/kg of complete feedingstuff with a moisture content of 12 %. - 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 %: — 14 mg/kg for cats; — 25 mg/kg for other species and categories.'	6 February 2027
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(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 14 mg/kg for cats; — 25 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 eye 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.	
2b01003	—	Pin-2(10)-ene	<i>Additive composition</i> Pin-2(10)-ene <i>Characterisation of the active substance</i> Pin-2(10)-ene Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₁₀H₁₆	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 %.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			CAS No 127-91-3 FLAVIS No: 01.003 <i>Method of analysis</i> ⁽¹⁾ For the determination of pin-2(10)-ene 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 %: 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 eye 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.	
2b01004	—	Pin-2(3)-ene	<i>Additive composition</i> Pin-2(3)-ene <i>Characterisation of the active substance</i> Pin-2(3)-ene	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.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₁₀H₁₆ CAS No 80-56-8 FLAVIS No: 01.004 <i>Method of analysis</i> ⁽¹⁾ For the determination of pin-2(3)-ene 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 eye 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.	
2b01007	—	beta-caryophyllene	Additive composition beta-caryophyllene	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
			<i>Characterisation of the active substance</i> beta-caryophyllene Produced by chemical synthesis Purity: min. 80 % Chemical formula: C₁₅H₂₄ CAS No 87-44-5 FLAVIS No: 01.007 <i>Method of analysis</i> ⁽¹⁾ For the determination of beta-caryophyllene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 eye 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.	
2b01009	—	Camphene	<i>Additive composition</i> Camphene	All animal species	—	—	—	1. The additive shall be incorporated into the feed in the form of a premixture.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
			<i>Characterisation of the active substance</i> Camphene Produced by chemical synthesis Purity: min. 80 % Chemical formula: C₁₀H₁₆ CAS No 79-92-5 FLAVIS No: 01.009 <i>Method of analysis</i> ⁽¹⁾ For the determination of camphene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.				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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 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 eye 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)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
2b01010	—	1-Isopropenyl-4-methylbenzene	<i>Additive composition</i> 1-Isopropenyl-4-methylbenzene <i>Characterisation of the active substance</i> 1-Isopropenyl-4-methylbenzene Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₁₀H₁₂ CAS No 1195-32-0 FLAVIS No:01.010 <i>Method of analysis</i> ⁽¹⁾ For the determination of 1-Isopropenyl-4-methylbenzene 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: for pigs and poultry: 1 mg/kg, and for other species and categories: 1,5 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 %: — 1 mg/kg for pigs and poultry; — 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: — 1 mg/kg for pigs and poultry; — 1,5 mg/kg for other species and categories.	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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 eye 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.	
2b01029	—	delta-3-Carene	<i>Additive composition</i> delta-3-Carene <i>Characterisation of the active substance</i> delta-3-Carene Produced by chemical synthesis Purity: min. 92 % Chemical formula: C₁₀H₁₆ CAS No 13466-78-9 FLAVIS No:01.029 <i>Method of analysis ⁽¹⁾</i> For the determination of delta-3-Carene 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 labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 5 mg/kg	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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 eye 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.	
2b01045	—	d-Limonene	<i>Additive composition</i> d-Limonene <i>Characterisation of the active substance</i> d-Limonene Produced by chemical synthesis Purity: min. 96 % Chemical formula: C ₁₀ H ₁₆ CAS No 5989-27-5 FLAVIS No: 01.045 <i>Method of analysis</i> ⁽¹⁾ For the determination of d-limonene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species except male rats	—	—	—	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.’ 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg	6 February 2027

(1)	(2)	(3)	(4)	(5)	(6)	(7)		(8)	(9)
								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 eye 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) 2017/66
of 14 December 2016
concerning the authorisation of tannic acid as a feed additive for all animal species
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Tannic acid was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That product was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (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 tannic acid as a feed additive for all animal species. The applicant requested that additive 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 11 September 2014 ⁽³⁾ that, under the proposed conditions of use in feed this substance does not have adverse effects on animal health, human health or the environment. The Authority further concluded that the function of tannic acid in feed is similar to that on food. The Authority has already concluded that for food tannic acid is efficacious, as it increases the food smell or palatability. Therefore, that conclusion can be extrapolated for feed.
- (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, compound feeds and feed materials.
- (6) The Authority concluded that in the absence of data on user safety tannic acid should be considered as potentially hazardous to the respiratory tract, skin, eyes and mucous membranes. 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 substance 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 tannic acid 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 tannic acid, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

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

⁽³⁾ EFSA Journal 2014;12(10):3828.

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

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category '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 those substances, which are produced and labelled before 6 August 2017 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 6 February 2018 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 6 February 2019 in accordance with the rules applicable before 6 February 2017 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 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, 14 December 2016.

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

2b16080	—	Tannic acid	<i>Additive composition</i> Tannic acid <i>Characterisation of the active substance</i> Tannic acid Produced by extraction from different plants. Purity: min. 93 % on dry matter basis Chemical formula: $C_{76}H_{52}O_{46}$ CAS number 72401-53-7 FLAVIS No: 16.080 <i>Method of analysis</i> ⁽¹⁾ For the determination of tannic acid, in the feed additive: Qualitative colorimetric or precipitation tests (Ph. Eur. 6th edition, monograph 1477) and quantitative gravimetric method (FAO JECFA tannic acid monograph).	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: 15 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 %: 15 mg/kg'. 5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuffs, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 15 mg/kg.	6 February 2027
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			For the identification of tannic acid (as gallic acid) in the premixture of flavourings: Reversed Phase High Performance Liquid Chromatography coupled to UV detector(RP-HPLC-UV).					6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by 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 safety glasses and gloves.	
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(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>

