# **COMMISSION IMPLEMENTING REGULATION (EU) 2022/1250**

# of 19 July 2022

concerning the authorisation of ethyl acrylate, pentyl isovalerate, butyl 2-methyl butyrate, 2-methylundecanal, (2E)-methylcrotonic acid, ethyl (E,Z)-deca-2,4-dienoate, butan-2-one, cyclohexyl acetate, 3,4-dimethylcyclopentan-1,2-dione, 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one, phenethyl butyrate, hexyl phenylacetate, 4-methylacetophenone, 4-methoxyacetophenone, 3-methylphenol, 3,4-dimethylphenol, 1-methoxy-4-methylbenzene, trimethyloxazole and 4,5-dihydrothiophen-3 (2H)-one 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 an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC (2).
- (2) The substances ethyl acrylate, pentyl isovalerate, butyl 2-methyl butyrate, 2-methylundecanal, (2E)-methylcrotonic acid, ethyl (E,Z)-deca-2,4-dienoate, butan-2-one, cyclohexyl acetate, 3,4-dimethylcyclopentan-1,2-dione, 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one, phenethyl butyrate, hexyl phenylacetate, 4-methylacetophenone, 4-methoxyacetophenone, 3-methylphenol, 3,4-dimethylphenol, 1-methoxy-4-methylbenzene, trimethyloxazole and 4,5-dihydrothiophen-3(2H)-one were authorised without a time limit in accordance with Directive 70/524/EEC as a feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) 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, several applications were submitted for the re-evaluation of those additives for all animal species.
- (4) The applicant requested the additives to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of flavouring compounds for use in water for drinking. Therefore, the use of these additives in water for drinking should not be allowed.
- (5) The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

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

- The European Food Safety Authority ('the Authority') concluded in its opinions of 1 February 2012 (3), 7 March (6)2012 (4), 25 April 2012 (5), 17 October 2012 (6), 12 March 2013 (7), 5 March 2014 (8), 20 October 2015 (9), 26 January 2016 (10), 8 March 2016 (11), 20 April 2016 (12), 25 May 2016 (13), 12 July 2016 (14) and 19 October 2016 (15), that, under the proposed conditions of use, the additives do not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that the additives should be considered as irritants to skin, eyes and respiratory tract and as skin sensitizers. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- The Authority concluded, that the additives are recognised to flavour food and its function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (8)The assessment of the additives 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.
- (9) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- The fact that the additives are not authorised for use as a flavourings in water for drinking does not preclude their use in compound feed which is administered via water.
- Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- 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 additives in animal nutrition, subject to the conditions laid down in that Annex.

- (3) EFSA Journal 2012;10(2):2573.
- (4) EFSA Journal 2012;10(3):2625.
- (5) EFSA Journal 2012;10(5):2678.
- (6) EFSA Journal 2012;10(10):2927.
- (7) EFSA Journal 2013;11(4):3169.
- (8) EFSA Journal 2014;12(3):3608.
- (9) EFSA Journal 2015;13(11):4268.
- (10) EFSA Journal 2016;14(2):4390.
- (11) EFSA Journal 2016;14(6):4441.
- (12) EFSA Journal 2016;14(6):4475.
- (13) EFSA Journal 2016;14(6):4512.
- (14) EFSA Journal 2016;14(8):4557.
- (15) EFSA Journal 2016;14(11):4618.

# Article 2

# **Transitional measures**

- 1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 9 February 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted.
- 2. Compound feed and feed materials containing these substances as specified in the Annex which are produced and labelled before 9 August 2023 in accordance with the rules applicable before 9 August 2022 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 these substances as specified in the Annex which are produced and labelled before 9 August 2024 in accordance with the rules applicable before 9 August 2022 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, 19 July 2022.

For the Commission The President Ursula VON DER LEYEN

Identification		Commonition showing	Cmasias an	Morri	Minimum content	Maximum content		
number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	mg of add complete for with a moistu	eedingstuff are content of	Other provisions	End of period of authorisation
	ensory additi group: Flavou	ives iring compounds						
2b09037	Ethylacrylate	Additive composition Ethyl acrylate Characterisation of active substance Ethyl acrylate Produced by chemical synthesis Purity: 97 % Chemical formula: C <sub>5</sub> H <sub>8</sub> O <sub>2</sub> CAS number: 140-88-5 FLAVIS: 09.037  Analytical method (¹) For the identification of ethyl acrylate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species				<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>pigs and poultry: 1 mg;</li> <li>other species or categories of animals: 1,5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>	

ANNEX

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluationreports\_en

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Identification number of the additive	Additive ensory additi	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	Minimum content  mg of addi complete fe with a moistu	eedingstuff re content of	-	Other provisions	End of period of authorisation
Functional g	group: Flavou	ring compounds							
2b09499	Pentyl isovalerate	Additive composition Pentyl isovalerate  Characterisation of active substance Pentyl isovalerate Produced by chemical synthesis Purity: 98 % Chemical formula: C <sub>10</sub> H <sub>20</sub> O <sub>2</sub> CAS number: 25415-62-7 FLAVIS: 09.499  Analytical method (¹) For the identification of pentyl isovalerate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<ol> <li>3.</li> <li>4.</li> </ol>	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 conditions and stability to heat treatment shall be indicated.  On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:  — pigs and poultry: 1 mg;  — other species or categories of animals: 1,5 mg.'  The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.  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 skin, eye and breathing protection.	

<sup>(</sup>¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	Minimum content  mg of add complete for with a moistu	eedingstuff re content of		of period of horisation
Category: S Functional §	ensory additi group: Flavou	ves rring compounds		I	l			
2b09519	Butyl 2-methyl butyrate	Additive composition Butyl 2-methyl butyrate  Characterisation of active substance Butyl 2-methyl butyrate Produced by chemical synthesis Purity: 95 % Chemical formula: C <sub>9</sub> H <sub>18</sub> O <sub>2</sub> CAS number: 15706-73-7 FLAVIS: 09.519  Analytical method (¹) For the identification of butyl 2-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	-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>pigs and poultry: 1 mg;</li> <li>other species or categories of animals: 1,5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>	igust 2032

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

Identification		Comments and annial	Consider an	Mari	Minimum content	Maximum content	
number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	mg of addi complete fe with a moistu 12	edingstuff re content of	Other provisions  End of period of authorisation
	ensory additi group: Flavou	ves ring compounds					
2b05077	decanal	Additive composition 2-Methylundecanal  Characterisation of active substance 2-Methylundecanal Produced by chemical synthesis Purity: 97 % Chemical formula: C <sub>12</sub> H <sub>24</sub> O CAS number: 110-41-8 FLAVIS: 05.077  Analytical method (¹) For the identification of 2-methylundecanal in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>pigs and poultry: 1 mg;</li> <li>other species or categories of animals: 1,5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluationreports\_en

Identification		Commentation of control	Currier ou	Mani	Minimum content	Maximum content		
number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	mg of addi complete fe with a moistu 12	eedingstuff re content of	Other provisions	End of period of authorisation
	ensory addit group: Flavou	ives iring compounds						
2b08064	(2E)- Methylcro- tonic acid	Additive composition (2E)-Methylcrotonic acid Characterisation of active substance (2E)-Methylcrotonic acid Produced by chemical synthesis Purity: min. 99 % Chemical formula: C <sub>5</sub> H <sub>8</sub> O <sub>2</sub> CAS number: 80-59-1 FLAVIS: 08.064  Analytical method (¹) For the identification of (2E)-methylcrotonic acid in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>marine animals: 0,05 mg;</li> <li>other species or categories of animals: 1 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>	

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

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Identification		Composition, chemical	Species or	Maxi-	content	content	
number of the additive	Additive	formula, description, analytical method	category of animal	mum age	mg of add complete f with a moistu 12	eedingstuff	Other provisions  End of period of authorisation
	ensory additi group: Flavou	ves ring compounds					
	T	T	T	Т	ı	1	
2b09260	Ethyl (E,Z)-dec-a-2,4-dieno-ate	Additive composition Ethyl (E,Z)- deca-2,4-dienoate	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture.
		Characterisation of active substance Ethyl (E,Z)-deca-2,4-dienoate					2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
		Produced by chemical synthesis Purity: min. 90 % Chemical formula: C <sub>12</sub> H <sub>20</sub> O <sub>2</sub> CAS number: 3025-30-7 FLAVIS: 09.260					3. On the label of the additive the following shall be indicated:  'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:  — marine animals: 0,05 mg;  — other species or categories of animals: 1 mg.'
		Analytical method (¹)					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.
		For the identification of ethyl (EZ)-deca-2,4-dienoate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with					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
		retention time locking					premixtures shall be used with personal protective equipment,

Minimum

content

GC-MS-RTL.

Maximum

content

including skin, eye and breathing protection.

<sup>(</sup>¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluationreports\_en

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	Minimum content  mg of add: complete fewith a moistu	eedingstuff re content of	Other provisions	End of period of authorisation
	ensory additi group: Flavou	ives cring compounds						
2b07053	Butan- 2-one	Additive composition Butan-2-one  Characterisation of active substance Butan-2-one Produced by chemical synthesis Purity: min. 99,5 % Chemical formula: C <sub>4</sub> H <sub>8</sub> O CAS number: 78-93-3 FLAVIS: 07.053  Analytical method (¹) For the identification of butan-2-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-		<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>pigs and poultry: 1 mg;</li> <li>other species or categories of animals: 1,5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>	

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

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End of period of authorisation



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2b09027	Cyclohexyl acetate	Additive composition Cyclohexyl acetate	All animal	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 9 August 203
		Characterisation of active substance	species				2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
		Cyclohexyl acetate Produced by chemical synthesis Purity: > 98 % Chemical formula: C <sub>8</sub> H <sub>14</sub> O <sub>2</sub> CAS number: 622-45-7					3. On the label of the additive the following shall be indicated:  'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:  — marine animals: 0,05 mg;  — other species or categories of animals: 1 mg.'
		FLAVIS: 09.027  Analytical method (¹)  For the identification of cyclohexyl acetate in the					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.
		feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 skin, eye and breathing protection.

Maximum

content

Other provisions

mg of additive/kg of complete feedingstuff with a moisture content of

12 %

Minimum content

Identification

number of the additive

Additive

Functional group: Flavouring compounds Cyclohexyl

**Category: Sensory additives** 

Composition, chemical

formula, description, analytical method

Species or

category

of animal

Maxi-

mum

age

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End of period of authorisation

2b07075	3,4-Dimethylcyclopen-	Additive composition 3,4-Dimethylcyclopentan-1,2-dione	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture.
	tan-1,2-dio- ne	Characterisation of active substance 3,4-Dimethylcyclopen-					2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
		tan-1,2-dione Produced by chemical synthesis Purity: > 98 % Chemical formula: C <sub>7</sub> H <sub>10</sub> O <sub>2</sub> CAS number: 13494-06-9 FLAVIS: 07.075					3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:  — cats and dogs: 5 mg;  — marine animals: 0,05 mg  — other species or categories of animals: 0,5 mg.'
		Analytical method (¹) For the identification of					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.
		3,4-dimethylcyclopentan-1,2-dione in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 skin, eye and breathing protection.

Minimum

content

mg of additive/kg of

complete feedingstuff with a moisture content of

12 %

Identification

number of the additive

Additive

Composition, chemical

formula, description, analytical method

Species or

category

of animal

Maxi-

mum

age

Maximum

content

Other provisions

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Identification number of the additive	Additive ensory addit	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	mg of addi complete fe with a moistu 12	eedingstuff re content of	Other provisions  End of period authorisation
		aring compounds					
2b10023	5-Ethyl- 3-hydroxy- 4-methyl- furan-2 (5H)-one	Additive composition 5-Ethyl-3-hydroxy- 4-methylfuran-2(5H)- one  Characterisation of active substance 5-Ethyl-3-hydroxy- 4-methylfuran-2(5H)- one  Produced by chemical synthesis Purity: 95 % Chemical formula: C <sub>7</sub> H <sub>10</sub> O <sub>3</sub> CAS number: 698–10–2 FLAVIS: 10.023  Analytical method (¹) For the identification of 5-ethyl-3-hydroxy- 4-methylfuran-2(5H)- one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-		-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         — marine animals: 0,05 mg;         — poultry and pigs: 0,05 mg;         — other species or categories of animals: 0,08 mg.'</li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>

Minimum

content

Maximum

content

<sup>(</sup>¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

Identification		Commentation of control	C	Maxi-	content	content	
number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	mum age	mg of addi complete fe with a moistu 12	eedingstuff are content of	Other provisions  End of period authorisation
Category: Se Functional §	ensory addit group: Flavo	ives uring compounds					
2b09168	Phenethyl butyrate	Additive composition Phenethyl butyrate  Characterisation of active substance Phenethyl butyrate Produced by chemical synthesis Purity: 97 % Chemical formula: C <sub>12</sub> H <sub>16</sub> O <sub>2</sub> CAS number: 103-52-6 FLAVIS: 09.168  Analytical method (¹) For the identification of phenethyl butyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>pigs and poultry: 1 mg;</li> <li>other species or categories of animals: 1,5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>

Minimum Maximum

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluationreports\_en

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Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	Minimum content  mg of addi complete fe with a moistu	eedingstuff re content of	Other provisions  End of period of authorisation
Category: So Functional g	ensory additi group: Flavou	ives iring compounds					
2b09804	Hexyl phenylace- tate	Additive composition Hexyl phenylacetate  Characterisation of active substance Hexyl phenylacetate Produced by chemical synthesis Purity: 97 % Chemical formula: C <sub>14</sub> H <sub>20</sub> O <sub>2</sub> CAS number: 5421-17-0 FLAVIS: 09.804  Analytical method (¹) For the identification of hexyl phenylacetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>pigs and poultry: 1 mg;</li> <li>other species or categories of animals: 1,5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

Identification	A 110.0	Composition, chemical	Species or		Minimum content mg of addi	Maximum content	End of period o
number of the additive	Additive	formula, description, analytical method	category of animal	mum age	complete fe with a moistu	eedingstuff are content of	Other provisions authorisation
Category: S Functional §	ensory additi group: Flavou	ives cring compounds					
2b07022	4-Methyla-cetophe-none	Additive composition 4-Methylacetophenone  Characterisation of active substance 4-Methylacetophenone Produced by chemical synthesis Purity: > 95 % Chemical formula: C <sub>9</sub> H <sub>10</sub> O CAS number: 122-00-9 FLAVIS: 07.022  Analytical method (¹) For the identification of 4-methylacetophenone in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.		-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>marine animals: 0,05 mg;</li> <li>cats: 1 mg;</li> <li>other species or categories of animals: 5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

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Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	mg of add complete for with a moisture 12	eedingstuff are content of	Other provisions	End of period of authorisation
	ensory additi group: Flavou	ves ring compounds						
2b07038	4-Methox-yacetophe-none	Additive composition 4-Methoxyacetophenone Characterisation of active substance 4-Methoxyacetophenone Produced by chemical synthesis Purity: > 97 % Chemical formula: C <sub>9</sub> H <sub>10</sub> O <sub>2</sub> CAS number: 100-06-1 FLAVIS: 07.038  Analytical method (¹) For the identification of 4-methoxyacetophenone in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-			<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>marine animals: 0,05 mg;</li> <li>cats: 1 mg;</li> <li>other species or categories of animals: 5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>	

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluationreports\_en

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	Minimum content  mg of addi complete fe with a moistu	edingstuff re content of	Other provisions  End of period of authorisation
Category: So Functional g	ensory addit group: Flavou	ives Iring compounds					
2b04026	3-Methyl- phenol	Additive composition 3-Methylphenol  Characterisation of active substance 3-Methylphenol Produced by chemical synthesis Purity: 98 % Chemical formula: C <sub>7</sub> H <sub>8</sub> O CAS number: 108-39-4 FLAVIS: 04.026  Analytical method (¹) For the identification of 3-methylphenol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: 5 mg.'</li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\_en

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Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	mg of addi complete fe with a moistu 12	eedingstuff re content of	Other provisions  End of period of authorisation
	ensory additi group: Flavou	ives iring compounds					
2b04048	3,4-Dimethylphenol	Additive composition 3,4-Dimethylphenol  Characterisation of active substance 3,4-Dimethylphenol Produced by chemical synthesis Purity: 98 % Chemical formula: C <sub>8</sub> H <sub>10</sub> O CAS number: 95-65-8 FLAVIS: 04.048  Analytical method (¹) For the identification of 3,4-dimethylphenol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: 5 mg.'</li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluationreports\_en

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Identification		1 '	Species or	mum age	Minimum content  mg of additive/kg of complete feedingstuff with a moisture content of 12 %		Other provisions	End of period of authorisation
number of the additive	Additive		category of animal					

**Category: Sensory additives** Functional group: Flavouring compounds

2b04015	1-Methoxy- 4-methyl- benzene	Additive composition 1-Methoxy- 4-methylbenzene	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture.
		Characterisation of active substance 1-Methoxy- 4-methylbenzene					2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
		Produced by chemical synthesis Purity: 99 % Chemical formula: C <sub>8</sub> H <sub>10</sub> O					3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: 1 mg.'
		CAS number: 104-93-8 FLAVIS: 04.015  Analytical method (¹)					4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.
		For the identification of 1-methoxy- 4-methylbenzene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.					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 skin, eye and breathing protection.

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Identification number of	Additive	Composition, chemical formula, description,	Species or category	mum	Minimum content  mg of add		Other provisions  End of period of authorisation
the additive	ensory addit	analytical method	of animal	age	complete feedingstuff with a moisture content of 12 %		
		iring compounds					
2b13169	Trimethy-loxazole	Additive composition Trimethyloxazole  Characterisation of active substance Trimethyloxazole Produced by chemical synthesis Purity: > 95 % Chemical formula: C <sub>6</sub> H <sub>9</sub> ON CAS number: 20662-84-4 FLAVIS: 13.169  Analytical method (¹) For the identification of trimethyloxazole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %:         <ul> <li>marine animals: 0,05 mg;</li> <li>poultry and pigs: 0,3 mg;</li> <li>other species or categories of animals: 0,5 mg.'</li> </ul> </li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>

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Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi- mum age	Minimum content  mg of add complete for with a moisture 12	eedingstuff re content of	Other provisions	End of period of authorisation
Functional g	<u> </u>	ring compounds	Г	Т	T	T		
2b15012	4,5-Dihy-drothio-phen-3(2H)-one	Additive composition 4,5-Dihydrothiophen-3 (2H)-one  Characterisation of active substance 4,5-Dihydrothiophen-3 (2H)-one Produced by chemical synthesis. Purity: 97 % Chemical formula: C <sub>4</sub> H <sub>6</sub> OS CAS number: 1003-04-9 FLAVIS: 15.012  Analytical method (¹) For the identification of 4,5-dihydrothiophen-3 (2H)-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<ol> <li>The additive shall be incorporated into the feed in the form of a premixture.</li> <li>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: 0,05 mg.'</li> <li>The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3.</li> <li>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 skin, eye and breathing protection.</li> </ol>	

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