



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/1923174/2024 CIS
(POOL/G5/2024/1923174/1923174-EN
CIS.docx)
[...] (2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of a preparation of cyanocobalamin (vitamin B₁₂)
produced with *Ensifer adhaerens* CGMCC 21299 as a feed additive for all animal species**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of a preparation of cyanocobalamin (vitamin B₁₂)
produced with *Ensifer adhaerens* CGMCC 21299 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 nutrition¹, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299 as a feed additive for all animal species, to be classified in the additive category ‘nutritional additives’ and in the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 22 March 2024² that, under the proposed conditions of use, the preparation of cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299 is safe for all animal species, consumers and the environment. The Authority further concluded that the preparation of cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299, due to the presence of nickel, is considered a skin and respiratory sensitiser. Inhalation and dermal exposure are considered a risk. Due to the lack of data, the Authority could not conclude on the potential of the preparation to be an eye irritant. The Authority concluded that the preparation is efficacious in meeting animals’ nutritional requirements when administered via feed. 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.

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² EFSA Journal. 2024;22:e8752.

- (5) In view of the above, the Commission considers that the preparation cyanocobalamin (vitamin B₁₂) produced with *Ensifer adhaerens* CGMCC 21299 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1
Authorisation

The preparation specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Entry into force

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi mum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a837	‘Cyanocobalamin’ or ‘Vitamin B ₁₂ ’	Additive composition Preparation with ≤ 1% of cyanocobalamin Nickel: maximum 0.5 mg/kg Solid form Characterisation of active substance Cyanocobalamin Chemical formula: C ₆₃ H ₈₈ CoN ₁₄ O ₁₄ P CAS number: 68-19-9 Purity: minimum 96% Produced by fermentation with <i>Ensifer adhaerens</i> CGMCC 21299 Analytical method¹ For the quantification of cyanocobalamin (vitamin B ₁₂) in the feed additive preparation and in compound feed: reversed phase high performance liquid chromatography coupled to spectrophotometric detection (HPLC-UV).	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

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>.



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/12988990/2023 CIS
(POOL/G5/2023/12988990/12988990-
EN CIS.docx)
[...](2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336
as a feed additive for grazing animals for milk production of bovine species, sheep, and
goats (holder of authorisation: International Animal Health Products Pty Ltd,
represented by GAB Consulting GmbH)**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336 as a feed additive for grazing animals for milk production of bovine species, sheep, and goats (holder of authorisation: International Animal Health Products Pty Ltd, represented by GAB Consulting GmbH)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336 as a feed additive. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of *Duddingtonia flagrans* NCIMB 30336 as a feed additive for all grazing animals, requesting that additive to be classified in the category ‘zootechnical additives’, in the functional group ‘other zootechnical additives’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 2 July 2020² and 14 November 2023³ that, the preparation of *Duddingtonia flagrans* NCIMB 30336 is safe for all dairy bovines, ovines and caprines, consumers and the environment under the proposed conditions of use with a margin of safety of 10. Due to the lack of data, it could not conclude on the safety of the additive for other grazing species/categories. The Authority considered that the preparation of *Duddingtonia flagrans* NCIMB 30336 is not irritant to skin and eyes but is irritant to the respiratory tract and a respiratory sensitiser, while no conclusion could be drawn on its skin sensitisation potential. The Authority further concluded that the preparation of *Duddingtonia flagrans* NCIMB 30336 can reduce the number of parasitic nematodes on pasture to the benefit of grazing animals when used at the recommended application rate of 3×10^4 chlamydospores/kg body weight and per day. It did not consider that there is a need for specific requirements of post-market monitoring. The

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/>.

² EFSA Journal. 2020;18(7):6208.

³ EFSA Journal. 2023;21:e8466.

Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) In view of the above, the Commission considers that the preparation of *Duddingtonia flagrans* NCIMB 30336 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for dairy cows, dairy cows of minor bovine species, dairy sheep and dairy goats, while the assessment process continues for grazing animals other than dairy cows, dairy cows of minor bovine species, dairy sheep and dairy goats. It is appropriate, for practical and control reasons, to express the dosage of the preparation per kilogram of complete feedingstuff and to provide for the additive to be used only in feed for grazing dairy cows, dairy cows of minor bovine species, dairy sheep and dairy goats. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1
Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Entry into force

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed 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
						Number of chlamydospores/kg of complete feedingstuff with a moisture content of 12%			
Category: zootechnical additives. Functional group: other zootechnical additives (reduction of the number of infective nematode larvae on pasture)									
4d27	International Animal Health Products Pty Ltd, represented by GAB Consulting GmbH	Duddingtonia flagrans NCIMB 30336	Additive composition Preparation of <i>Duddingtonia flagrans</i> NCIMB 30336 containing a minimum of 5 x 10 ⁵ chlamydospores/g additive. Solid form. Characterisation of the active substance Viable chlamydospores of <i>Duddingtonia flagrans</i> NCIMB 30336 Analytical method ⁽¹⁾ For the identification of <i>Duddingtonia flagrans</i> NCIMB 30336: DNA based methods. For the enumeration of viable chlamydospores of <i>Duddingtonia flagrans</i> NCIMB 30336 in the feed additive, premixtures and compound feed: the method using yeast mannitol agar (YMA) with streptomycin and chloramphenicol and a	Dairy cows	-	8.5 x 10 ⁵	8.5 x 10 ⁶	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall only be used in feed for grazing animals. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]
				Dairy cows of minor bovine species					
				Dairy sheep					
				Dairy goats					

⁽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.

			most probable number (MPN) for the enumeration.						
--	--	--	--	--	--	--	--	--	--



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/9232772/2022 CIS
(POOL/G5/2022/9232772/9232772-EN
CIS.docx)
[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of *glycosylated 1,25-dihydroxycholecalciferol* from *Solanum glaucophyllum* extract as a feed additive for dairy cows

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of *glycosylated 1,25-dihydroxycholecalciferol* from *Solanum glaucophyllum* extract as a feed additive for dairy cows

(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 nutrition¹, 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract as a feed additive for dairy cows and other dairy ruminants, requesting that additive to be classified in the category ‘nutritional additives’ and in the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’. The preparation is intended to be used only in a complementary feed consisting of an encapsulated, controlled-release bolus to reduce the risk of milk fever and subclinical hypocalcaemia.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 29 June 2022² that the preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract, as applied in the animal studies evaluated, is safe for dairy cows when administered in a bolus containing 500µg of 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract once during the pre-parturient period (from 9 days before calving to immediately before calving). In the animal studies evaluated, the bolus was complemented by a feed containing appropriate levels of calcium and magnesium. Owing to a lack of data, the Authority was neither in the position to conclude on the safety of the subsequent administration

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² EFSA Journal 2022;20(8):7434.

of a second bolus as recommended by the applicant, if the cow has not calved within 9 days after bolus administration, nor on the safety for use in dairy ruminants other than cows (*Bos taurus*). It further concluded that the preparation is safe for consumers and the environment and that it is not irritating to skin and eyes and it is not a sensitiser. It considered that exposure via inhalation is unlikely when used in a bolus. The Authority concluded that the administration of the additive in a bolus containing 500µg of 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract in a period from 9 days before calving to immediately before calving has the potential to prevent hypocalcaemia in dairy cows when applied as in the animal studies evaluated. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) Subsequently, the applicant withdrew the application for authorisation of the preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract for all dairy ruminants except for dairy cows.
- (6) The Commission considers that the active substance of the feed additive is the glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract. The feed additive consists of a preparation containing the active substance that is stabilised with maltodextrin or other suitable carriers. The preparation is subsequently to be incorporated in a bolus that is regarded as a complementary feed.
- (7) The assessment of the preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised for the sole use in a complementary feed in the form of a bolus.
- (8) In addition, for safety reasons, the Commission considers that the maximum release level of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract released from the bolus in the body of the animals should be indicated as maximum content of complete feed. Taking into account that glycosylated 1,25-hydroxycholecalciferol is a precursor of 25-hydroxycholecalciferol and that the Authority stated in its opinion of 5 July 2023³ concerning 25-hydroxycholecalciferol produced with *Saccharomyces cerevisiae* CBS 146008 that no conclusion on the potential of that substance to be a skin sensitiser or on its effects on the respiratory system could be reached due to absence of data, the Commission considers that appropriate breathing and skin protective measures should be taken to prevent adverse effects on the health of the users of the additive, when handling the substance in view of the incorporation in a bolus. Furthermore, the Commission considers that as 25-hydroxycholecalciferol depresses the activity of 1α-hydroxylase in the kidney, the simultaneous use of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract with that additive should not be allowed.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

³ EFSA Journal 2023;21(8):8168.

HAS ADOPTED THIS REGULATION:

Article 1
Authorisation

The preparation specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Entry into force

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						mg of 1,25- dihydroxycholecalciferol /kg of complete feedingstuff with a moisture content of 12 %		
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect. Subclassification: Vitamin D								
3a673	Glycosylated 1,25- dihydroxycholecalciferol from <i>Solanum glaucophyllum</i> extract	Additive composition Preparation of <i>Solanum glaucophyllum</i> extract with a minimum of 0,005 % of glycosylated 1,25- dihydroxycholecalciferol Solid form Characterisation of active substance Glycosylated 1,25- dihydroxycholecalciferol Chemical formula: C ₂₇ H ₄₄ O ₃ ·*(C ₆ H ₁₀ O ₅) _n , where n= 1 to 12 CAS number: 89457-77-2 Produced by ethanolic extraction of leaves of <i>Solanum glaucophyllum</i>	Dairy cows	-	-	0,004	<div><div>1.</div><div>The additive shall be only used for incorporation in a complementary feed (in the form of a bolus) to reduce the risk of milk fever and subclinical hypocalcaemia.</div></div> <div><div>2.</div><div>The use of the additive shall be allowed only once during the pre-parturient period (from 9 days before calving to immediately before calving).</div></div> <div><div>3.</div><div>The additive is administered once in a form of bolus with daily administration of:<div><div>–</div><div>a minimum of calcium of 60 g per cow during one week before calving and 84 g per day until the end of the third week of lactation;</div></div><div><div>–</div><div>a minimum of magnesium of 18 g per</div></div></div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						mg of 1,25- dihydroxycholecalciferol /kg of complete feedingstuff with a moisture content of 12 %		
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect. Subclassification: Vitamin D								
		Analytical method ¹ For the quantification of glycosylated 1,25-dihydroxycholecalciferol in the feed additive and in the feed (bolus): – Liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS).					cow during one week before calving and 26 g until the end of the third week of lactation. 4. The directions for use of the additive shall indicate the storage conditions. 5. Maximum content of the combination of glycosylated 1,25-dihydroxycholecalciferol with vitamin D ₃ (cholecalciferol) per kg of complete feed: 0,1 mg ² . 6. Simultaneous use of the additive with 25-hydroxycholecalciferol shall not be permitted. 7. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks	

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

² 40 IU cholecalciferol (vitamin D₃)= 0,001 mg cholecalciferol (vitamin D₃).

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
						mg of 1,25- dihydroxycholecalciferol /kg of complete feedingstuff with a moisture content of 12 %		
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect. Subclassification: Vitamin D								
							resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/12792929/2023 CIS
(POOL/G5/2023/12792929/12792929-
EN CIS.docx)
[...](2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**concerning the authorisation of benzoic acid as a feed additive for weaned piglets and
pigs for fattening (holder of authorisation: LANXESS Chemical B.V.)**

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of benzoic acid as a feed additive for weaned piglets and pigs for fattening (holder of authorisation: LANXESS Chemical B.V.)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of benzoic acid as a feed additive. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of benzoic acid as a feed additive for weaned piglets and pigs for fattening, requesting that additive to be classified in the category ‘zootechnical additives’, in the functional group ‘other zootechnical additives’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 14 November 2023² that, under the proposed conditions of use, benzoic acid is safe for weaned piglets and pigs for fattening, consumers and the environment under the proposed conditions of use. It also concluded that benzoic acid poses a risk by inhalation, is irritant to skin and corrosive to eyes, but that due to the lack of data no conclusions can be drawn on dermal sensitisation. The Authority further concluded that benzoic acid is efficacious as a zootechnical feed additive for weaned piglets up to 25 kg and for pigs for fattening. It did not consider that there is a need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005³, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² EFSA Journal. 2023;21:e8454.

³ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

assessment concerning the same active substance⁴ are valid and applicable for the current application.

- (6) In view of the above, the Commission considers that benzoic acid satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. It is appropriate to provide for the additive not to be used with other sources of benzoic acid or benzoates, and to be fed only thoroughly mixed with other feed materials of the daily ration. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) 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 ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Entry into force

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

⁴ Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/publications/fad-2010-0029_en.

ANNEX

Identification number of the feed 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: zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters: weight gain or feed to gain ratio)									
4d211	LANXESS Chemical B.V.	Benzoic acid	<p>Additive composition Benzoic acid (≥ 99,9 %) Solid form.</p> <p>Characterisation of the active substance Benzoic acid (also known as benzenecarboxylic acid and phenylcarboxylic acid) C₇H₆O₂ CAS number 65-85-0 Maximum level of the impurities: Phthalic acid: ≤ 100 mg/kg Biphenyl: ≤ 100 mg/kg</p> <p>Analytical method ⁽¹⁾ For the determination of benzoic acid in the feed additive, premixtures and compound feed: high performance liquid chromatography with ultraviolet detection</p>	Weaned piglets	-	5000	5000	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall not be used with other sources of benzoic acid or benzoates. 3. In the directions for use of the additive, premixtures and compound feed the following shall be indicated: ‘Complementary feedingstuff containing benzoic acid shall only be fed to weaned piglets if thoroughly mixed with other feed materials of the daily ration’ 4. The additive shall	<i>[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]</i>

⁽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

			(HPLC-UV) - EN 17298					only be used in weaned piglets up to 25 kg of body weight. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	
Category: zootechnical additives. Functional group: other zootechnical additives (urinary pH decrease)									
4d211	LANXESS Chemical B.V.	Benzoic acid	<p>Additive composition Benzoic acid ($\geq 99,9\%$) Solid form.</p> <p>Characterisation of the active substance Benzoic acid (also known as benzenecarboxylic acid and phenylcarboxylic acid) $C_7H_6O_2$ CAS number 65-85-0 Maximum level of the impurities: Phthalic acid: ≤ 100 mg/kg Biphenyl: ≤ 100 mg/kg</p> <p>Analytical method ⁽¹⁾ For the determination of</p>	Pigs for fattening	-	5000	10000	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. The additive shall not be used with other sources of benzoic acid or benzoates.</p> <p>3. In the directions for use of the additive, premixtures and compound feed the following shall be indicated: 'Complementary feedingstuff containing</p>	<p>[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]</p>

			benzoic acid in the feed additive, premixtures and compound feed: high performance liquid chromatography with ultraviolet detection (HPLC-UV) - EN 17298					benzoic acid shall only be fed to pigs for fattening if thoroughly mixed with other feed materials of the daily ration' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	
--	--	--	--	--	--	--	--	---	--



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10986861/2023
[...] (2023) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

concerning the authorisation of undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiacol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene as feed additives for all animal species and amending Implementing Regulation (EU) 2018/245 as regards the terms of authorisation of d,l-isomenthone as a feed additive for all animal species

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiaicol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene as feed additives for all animal species and amending Implementing Regulation (EU) 2018/245 as regards the terms of authorisation of d,l-isomenthone 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 nutrition¹, and in particular Articles 9(2) and 13(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and modifying such authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (2) The substances undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiaicol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of Feed Additives as existing products belonging

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1., ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

to the functional group of flavouring compounds, in accordance with Article 10(1), point (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, nine applications were submitted for the authorisation of undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiacol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene ('the substances concerned') as feed additives for all animal species. The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The applicant requested the substances concerned 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 applicant withdrew the application for water for drinking for all the substances concerned.
- (5) The use of d,l-isomenthone as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) 2018/245³.
- (6) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of d,l-isomenthone as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, considering a modification of the terms of that authorisation. That modification consists in an increase of the maximum recommended level of d,l-isomenthone to 5 mg/kg for all animal species. The request was accompanied by the relevant supporting data.
- (7) The Authority concluded in its opinions of 1 February 2012⁴, 6 March 2012⁵, 7 March 2012⁶, 13 June 2012⁷, 13 November 2012⁸, 10 March 2015⁹, 8 March 2016¹⁰, 20 April 2016¹¹, 12 July 2016¹² and 26 September 2023¹³ that, under the proposed conditions of

³ Commission Implementing Regulation (EU) 2018/245 of 15 February 2018 concerning the authorisation of menthol, d-carvone, menthyl acetate, d,l-isomenthone, 3-methyl-2-(pent-2(cis)-enyl)cyclopent-2-en-1-one, 3,5,5-trimethylcyclohex-2-en-1-one, d-fenchone, fenchyl alcohol, carvyl acetate, dihydrocarvyl acetate and fenchyl acetate as feed additives for all animal species (OJ L 53, 23.2.2018, p. 87, ELI: http://data.europa.eu/eli/reg_impl/2018/245/oj).

⁴ EFSA Journal 2012;10(2):2573.

⁵ EFSA Journal 2012;10(3):2622.

⁶ EFSA Journal 2012;10(3):2625.

⁷ EFSA Journal 2012;10(7):2785.

⁸ EFSA Journal 2012;10(11):2966.

⁹ EFSA Journal 2015;13(3):4053.

¹⁰ EFSA Journal 2016;14(6):4441.

¹¹ EFSA Journal 2016;14(6):4475.

¹² EFSA Journal 2016;14(8):4559.

¹³ EFSA Journal 2023;21(10):8340.

use, the substances concerned are safe for all animal species, consumers and the environment. It stated that for 2-methoxyphenol, thymol, 2-methoxy-4-methylphenol, 4-ethylguaiaicol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, carvacrol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol and benzene-1,3-diol no new data on the safety for the user was provided but that potential hazards for skin and eye contact and respiratory exposure of various severity are recognised for these substances. For 3-butylidenephthalide and 3-propylidenephthalide the material safety data sheets provided by the suppliers identify those substance as irritant to skin, eye and the respiratory tract and harmful if swallowed. For phenylacetaldehyde, phenylacetic acid, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, methyl salicylate and 3-methylbutyl phenylacetate, the Authority considered it prudent to treat all those compounds as irritants to skin, eyes and respiratory tract, skin sensitisers and harmful if swallowed. For terpineol acetate, it considered it prudent to treat it as irritant to skin, eyes and respiratory tract and as skin sensitiser. Terpinolene, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene should be considered irritant to skin, eyes and respiratory tract and as skin sensitisers. The Authority stated that for benzothiazole, d,l-borneol, d,l-isoborneol, l-carvone, trans-menthone, d-camphor, d,l-bornyl acetate, undec-10-enal and d,l-isobornyl acetate, hazards for skin and eye contact and respiratory exposure are recognised and that they are classified as irritating to the respiratory system. The Authority finally concluded that all the substances concerned are recognised to flavour food and their function in feed would be essentially the same as that in food and therefore that no further demonstration of efficacy is considered necessary. The Authority considered that there was no need for specific requirements of post-market monitoring. The Authority 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. Furthermore, the Authority concluded in the opinion of 26 September 2023 that for d,l-isomenthone, the maximum recommended level of 5 mg/kg is safe for all animal species, consumers and the environment.

- (8) In view of the above, the Commission considers that the substances concerned satisfy the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003. In addition, the Commission considers that the authorisation of d,l-isomenthone still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, when modifying the terms thereof as regards the increase of the maximum recommended level to 5 mg/kg for all animal species. Accordingly, the use of the substances concerned should be authorised and the terms of authorisation for d,l-isomenthone should be modified. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the substances concerned.
- (9) The Commission considers that for l-carvone, methyl salicylate, thymol and carvacrol, safety reasons require the establishments of maximum contents and that those additives cannot be used in combination with other additives containing such substances. For undec-10-enal, terpineol acetate, d,l borneol, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiaicol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-

dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene safety reasons do not require the setting of maximum contents. However, in order to allow better control, a recommended maximum content should be indicated on the label of those additives. Where the recommended maximum content is exceeded, certain information should be indicated on the label of the premixtures concerned.

- (10) Implementing Regulation (EU) 2018/245 should therefore be amended accordingly.
- (11) 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 provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation. In addition, since safety reasons do not require the immediate application of the modification to the terms of authorisation for d,l-isomenthone, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the requirements resulting from that modification.
- (12) 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.

Article 2 *Amendment to Implementing Regulation (EU) 2018/245*

In the entry for d,l-isomenthone in the Annex to Implementing Regulation (EU) 2018/245, points 3 to 5 of the column “Other provisions” are replaced by the following:

“3. On the label of the additive the following shall be indicated: “Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 5 mg/kg for all animal species.

“ 4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level suggested on the label of the premixture would result in exceeding the level referred to in point 3.”

5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feedingstuff with a moisture content of 12 % exceeds 5 mg/kg for all animal species.”.

Article 3

Transitional measures

1. The feed additives undec-10-enal, terpineol acetate, d,l borneol, l-carvone, d-camphor, d,l-isobornyl acetate, 3-propylidenephthalide, phenylacetic acid, methyl salicylate, thymol, carvacrol, benzothiazole, terpinolene, d,l-isoborneol, trans-menthone, d,l-bornyl acetate, 3-butylidenephthalide, phenylacetaldehyde, phenethyl acetate, phenethyl phenylacetate, methyl phenylacetate, ethyl phenylacetate, isobutyl phenylacetate, 3-methylbutyl phenylacetate, 2-methoxyphenol, 2-methoxy-4-methylphenol, 4-ethylguaiacol, 2-methoxy-4-vinylphenol, 4-ethylphenol, 2-methylphenol, 4-methylphenol, 2,6-dimethoxyphenol, phenol, 2,6-dimethylphenol, 2-isopropylphenol, benzene-1,3-diol, alpha-phellandrene, alpha-terpinene, gamma-terpinene and l-limonene, as authorised pursuant to Directive 70/524/EEC, and the feed additive d,l-isomenthone (identification number: 2b07078) authorised by Implementing Regulation (EU) 2018/245, and premixtures containing these feed additives, which are produced and labelled before *[6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before *[12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before *[24 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

Article 4

Entry into force

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b05035	Undec-10-enal	Additive composition Undec-10-enal Characterisation of active substance Undec-10-enal Produced by chemical synthesis Purity: min. 94% Chemical formula: C ₁₁ H ₂₀ O CAS number: 112-45-8 FLAVIS: 05.035 ----- Analytical method¹ For the identification of undec-10-enal in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>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."</div><div>4.</div><div>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.</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09830	Terpineol acetate	Additive composition Terpineol acetate Characterisation of active substance Terpineol acetate Produced by chemical synthesis Purity: min. 96. % Chemical formula: C ₁₂ H ₂₀ O ₂ CAS number: 8007-35-0 FLAVIS: 09.830 ----- Analytical method² For the identification of terpineol acetate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>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%: 10 mg."</div></div> <div><div>4.</div><div>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.</div></div> <div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

² 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b02016	d,l-Borneol	Additive composition d,l-Borneol Characterisation of active substance d,l-Borneol Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₀ H ₁₈ O CAS number: 507-70-0 FLAVIS: 02.016 ----- Analytical method³ For the identification of d,l-borneol in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>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%: 15 mg."</div></div> <div><div>4.</div><div>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.</div></div> <div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

³ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b07147	l-Carvone	Additive composition l-Carvone Characterisation of active substance l-Carvone Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₀ H ₁₄ O CAS number: 6485-40-1 FLAVIS: 07.147 ----- Analytical method⁴ For the identification of l-carvone in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	10	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>3. The additive shall not be used with other sources of l- carvone.</div> <div>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.</div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

⁴ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b07215	d-Camphor ⁵	Additive composition d-Camphor Characterisation of active substance d-Camphor Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₁₀ H ₁₆ O CAS number: 464-49-3 FLAVIS: 07.215 ----- Analytical method⁶ For the identification of d-camphor in the feed additive and in feed flavouring premixtures: <div>- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.</div>	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>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."</div><div>4.</div><div>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.</div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and</div></div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

⁵ Synonym: (1R)-1,7,7-Trimethylbicyclo[2.2.1]heptan-2-one

⁶ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09218	d,l-Isobornyl acetate	Additive composition d,l-Isobornyl acetate Characterisation of active substance d,l-Isobornyl acetate Produced by chemical synthesis Purity: min. 97 % Chemical formula: C ₁₂ H ₂₀ O ₂ CAS number: 125-12-2 FLAVIS: 09.218 ----- Analytical method⁷ For the identification of d,l-isobornyl acetate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>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."</div></div> <div><div>4.</div><div>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.</div></div> <div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and</div></div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

⁷ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b10005	3-Propylidenephthalide	Additive composition 3-Propylidenephthalide Characterisation of active substance 3-Propylidenephthalide Produced by chemical synthesis Purity: min.96% Chemical formula: C ₁₁ H ₁₀ O ₂ CAS number: 17369-59-4 FLAVIS: 10.005 ----- Analytical method⁸ For the identification of 3- propylidenephthalide in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

⁸ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b08038	Phenylacetic acid	Additive composition Phenylacetic acid Characterisation of active substance Phenylacetic acid Produced by chemical synthesis Purity: min. 99 % Chemical formula: C ₈ H ₈ O ₂ CAS number: 103-82-2 FLAVIS: 08.038 ----- Analytical method⁹ For the identification of phenylacetic acid in the feed additive and in feed flavouring premixtures: <div>- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.</div>	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 25 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

⁹ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09749	Methyl salicylate	Additive composition Methyl salicylate Characterisation of active substance Methyl salicylate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₈ H ₈ O ₃ CAS number: 119-36-8 FLAVIS: 09.749 ----- Analytical method¹⁰ For the identification of methyl salicylate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	50	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>The additive shall not be used with other sources of methyl salicylate.</div><div>4.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

¹⁰ 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.

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04006	Thymol	Additive composition Thymol Characterisation of active substance Thymol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₁₄ O CAS number: 89-83-8 FLAVIS: 04.006 ----- Analytical method¹¹ For the identification of thymol in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	125	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>The additive shall not be used with other sources of thymol.</div><div>4.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.</div></div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

¹¹ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04031	Carvacrol	Additive composition Carvacrol Characterisation of active substance Carvacrol Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₀ H ₁₄ O CAS number: 499-75-2 FLAVIS: 04.031 ----- Analytical method¹² For the identification of carvacrol in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	125	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>The additive shall not be used with other sources of carvacrol.</div></div> <div><div>4.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

¹² Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b15016	Benzothiazole	Additive composition Benzothiazole Characterisation of active substance Benzothiazole Produced by chemical synthesis Purity: min. 96% Chemical formula: C ₇ H ₅ NS CAS number: 95-16-9 FLAVIS: 15.016 ----- Analytical method¹³ For the identification of benzothiazole in the feed additive and in feed flavouring premixtures: <div>- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.</div>	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>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%: 0,5 mg."</div><div>4.</div><div>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.</div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

¹³ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b01005	Terpinolene	Additive composition Terpinolene Characterisation of active substance Terpinolene Produced by chemical synthesis or by fractional or steam distillation of essential oils. Purity: min. 95% Chemical formula: C ₁₀ H ₁₆ CAS number: 586-62-9 FLAVIS: 01.005 ----- Analytical method¹⁴ For the identification of terpinolene in the feed additive and in feed flavouring premixtures: <div>- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.</div>	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 14,5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

¹⁴ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b02059	<i>d,l</i> -Isoborneol	Additive composition <i>d,l</i> -Isoborneol Characterisation of active substance <i>d,l</i> -Isoborneol Produced by chemical synthesis Purity: min. 95% Chemical formula: C ₁₀ H ₁₈ O CAS number: 124-76-5 FLAVIS: 02.059 ----- Analytical method¹⁵ For the identification of <i>d,l</i> -isoborneol in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>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."</div></div> <div><div>4.</div><div>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.</div></div> <div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

¹⁵ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b07176	trans-Menthone	Additive composition trans-Menthone Characterisation of active substance trans-Menthone Produced by chemical synthesis Purity: min. 96% Chemical formula: C ₁₀ H ₁₈ O CAS number: 89-80-5 FLAVIS: 07.176 ----- Analytical method¹⁶ For the identification of trans-menthone in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

¹⁶ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09017	<i>d,l</i> -Bornyl acetate	Additive composition <i>d,l</i> -Bornyl acetate Characterisation of active substance <i>d,l</i> -Bornyl acetate Produced by chemical synthesis Purity: min. 98 % Chemical formula: C ₁₂ H ₂₀ O ₂ CAS number: 76-49-3 FLAVIS: 09.017 ----- Analytical method¹⁷ For the identification of <i>d,l</i> -bornyl acetate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>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."</div><div>4.</div><div>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.</div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

¹⁷ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b10024	3-Butylidenephthalide	Additive composition 3-Butylidenephthalide Characterisation of active substance 3-Butylidenephthalide Produced by chemical synthesis Purity: min. 99% Chemical formula: C ₁₂ H ₁₂ O ₂ CAS number: 551-08-6 FLAVIS: 10.024 ----- Analytical method¹⁸ For the identification of 3- butylidenephthalide in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>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."</div></div> <div><div>4.</div><div>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.</div></div> <div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

¹⁸ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b05030	Phenylacetaldehyde	Additive composition Phenylacetaldehyde Characterisation of active substance Phenyl acetaldehyde Produced by chemical synthesis Purity: min. 95% Chemical formula: C ₈ H ₈ O CAS number: 122-78-1 FLAVIS: 05.030 ----- Analytical method¹⁹ For the identification of phenylacetaldehyde in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

¹⁹ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09031	Phenethyl acetate	Additive composition Phenethyl acetate Characterisation of active substance Phenethyl acetate Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₁₀ H ₁₂ O ₂ CAS number: 103-45-7 FLAVIS: 09.031 ----- Analytical method²⁰ For the identification of phenethyl acetate in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²⁰ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09707	Phenethyl phenylacetate	Additive composition Phenethyl phenylacetate Characterisation of active substance Phenethyl phenylacetate Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₁₆ H ₁₆ O ₂ CAS number: 102-20-5 FLAVIS: 09.707 ----- Analytical method²¹ For the identification of phenethyl phenylacetate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²¹ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09783	Methyl phenylacetate	Additive composition Methyl phenylacetate Characterisation of active substance Methyl phenylacetate Produced by chemical synthesis Purity: min. 97% Chemical formula: C ₉ H ₁₀ O ₂ CAS number: 101-41-7 FLAVIS: 09.783 ----- Analytical method²² For the identification of methyl phenylacetate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 10 g."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²² 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09784	Ethyl phenylacetate	Additive composition Ethyl phenylacetate Characterisation of active substance Ethyl phenylacetate Produced by chemical synthesis Purity: min. 97% Chemical formula: C ₁₀ H ₁₂ O ₂ CAS number: 101-97-3 FLAVIS: 09.784 ----- Analytical method²³ For the identification of ethyl phenylacetate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 10 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²³ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09788	Isobutyl phenylacetate	Additive composition Isobutyl phenylacetate Characterisation of active substance Isobutyl phenylacetate Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₁₂ H ₁₆ O ₂ CAS number: 102-13-6 FLAVIS: 09.788 ----- Analytical method²⁴ For the identification of isobutyl phenylacetate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 10 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²⁴ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b09789	3-Methylbutyl phenylacetate	Additive composition 3-Methylbutyl phenylacetate Characterisation of active substance 3-Methylbutyl phenylacetate Produced by chemical synthesis Purity: min. 97% Chemical formula: C ₁₃ H ₁₈ O ₂ CAS number: 102-19-2 FLAVIS: 09.789 ----- Analytical method²⁵ For the identification of 3-methylbutyl phenylacetate in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 25 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²⁵ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04005	2-Methoxyphenol	Additive composition 2-Methoxyphenol Characterisation of active substance 2-Methoxyphenol Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₇ H ₈ O ₂ CAS number: 90-05-1 FLAVIS: 04.005 ----- Analytical method²⁶ For the identification of 2- methoxyphenol in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²⁶ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04007	2-Methoxy-4-methylphenol	Additive composition 2-Methoxy-4-methylphenol Characterisation of active substance 2-Methoxy-4-methylphenol Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₈ H ₁₀ O ₂ CAS number: 93-51-6 FLAVIS: 04.007 ----- Analytical method²⁷ For the identification of 2-methoxy-4-methylphenol in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²⁷ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04008	4-Ethylguaiaicol	Additive composition 4-Ethylguaiaicol Characterisation of active substance 4-Ethylguaiaicol Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₉ H ₁₂ O ₂ CAS number: 2785-89-9 FLAVIS: 04.008 ----- Analytical method²⁸ For the identification of 4-ethylguaiaicol in the feed additive and in feed flavouring premixtures: <div>- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.</div>	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²⁸ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04009	2-Methoxy-4-vinylphenol	Additive composition 2-Methoxy-4-vinylphenol Characterisation of active substance 2-Methoxy-4-vinylphenol Produced by chemical synthesis Purity: min. 96% Chemical formula: C ₉ H ₁₀ O ₂ CAS number: 7786-61-0 FLAVIS: 04.009 ----- Analytical method²⁹ For the identification of 2-methoxy-4-vinylphenol in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

²⁹ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04022	4-Ethylphenol	Additive composition 4-Ethylphenol Characterisation of active substance 4-Ethylphenol Produced by chemical synthesis Purity: min. 99% Chemical formula: C ₈ H ₁₀ O CAS number: 123-07-9 FLAVIS: 04.022 ----- Analytical method³⁰ For the identification of 4-ethylphenol in the feed additive and in feed flavouring premixtures: <div>- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.</div>	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>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."</div><div>4.</div><div>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.</div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

³⁰ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04027	2-Methylphenol	Additive composition 2-Methylphenol Characterisation of active substance 2-Methylphenol Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₇ H ₈ O CAS number: 95-48-7 FLAVIS: 04.027 ----- Analytical method³¹ For the identification of 2-methylphenol in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>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."</div><div>4.</div><div>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.</div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

³¹ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04028	4-Methylphenol	Additive composition 4-Methylphenol Characterisation of active substance 4-Methylphenol Produced by chemical synthesis Purity: min. 99% Chemical formula: C ₇ H ₈ O CAS number: 106-44-5 FLAVIS: 04.028 ----- Analytical method ³² For the identification of 4-methylphenol in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

³² 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04036	2,6-Dimethoxyphenol	Additive composition 2,6-Dimethoxyphenol Characterisation of active substance 2,6-Dimethoxyphenol Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₈ H ₁₀ O ₃ CAS number: 91-10-1 FLAVIS: 04.036 ----- Analytical method³³ For the identification of 2,6- dimethoxyphenol in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

³³ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04041	Phenol	Additive composition Phenol Characterisation of active substance Phenol Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₆ H ₆ O CAS number: 108-95-2 FLAVIS: 04.041 ----- Analytical method³⁴ For the identification of phenol in the feed additive and in feed flavouring premixtures: <div>- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.</div>	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

³⁴ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04042	2,6-Dimethylphenol	Additive composition 2,6-Dimethylphenol Characterisation of active substance 2,6-Dimethylphenol Produced by chemical synthesis Purity: min. 99% Chemical formula: C ₈ H ₁₀ O CAS number: 576-26-1 FLAVIS: 04.042 ----- Analytical method³⁵ For the identification of 2,6- dimethylphenol in the feed additive and in feed flavouring premixtures: <div>- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.</div>	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div><div>3.</div><div>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."</div><div>4.</div><div>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.</div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

³⁵ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04044	2-Isopropylphenol	Additive composition 2-Isopropylphenol Characterisation of active substance 2-Isopropylphenol Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₉ H ₁₂ O CAS number: 88-69-7 FLAVIS: 04.044 ----- Analytical method³⁶ For the identification of 2- isopropylphenol in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

³⁶ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04047	Benzene-1,3-diol ³⁷	Additive composition Benzene-1,3-diol Characterisation of active substance Benzene-1,3-diol Produced by chemical synthesis Purity: min. 98% Chemical formula: C ₆ H ₆ O ₂ CAS number: 108-46-3 FLAVIS: 04.047 ----- Analytical method ³⁸ For the identification of benzene-1,3-diol in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>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."</div></div> <div><div>4.</div><div>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.</div></div> <div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

³⁷ Synonym : Resorcinol.

³⁸ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b01006	alpha-Phellandrene	Additive composition alpha-Phellandrene Characterisation of active substance alpha-Phellandrene Produced by chemical synthesis or by fractional or steam distillation of essential oils. Purity: min. 95% Chemical formula: C ₁₀ H ₁₆ CAS number: 99-83-2 FLAVIS: 01.006 ----- Analytical method ³⁹ For the identification of alpha- phellandrene in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>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."</div></div> <div><div>4.</div><div>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.</div></div> <div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

³⁹ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b01019	alpha-Terpinene	Additive composition alpha-Terpinene Characterisation of active substance alpha-Terpinene Produced by chemical synthesis or by fractional or steam distillation of essential oils. Purity: min. 89 % Chemical formula: C ₁₀ H ₁₆ CAS number: 99-86-5 FLAVIS: 01.019 ----- Analytical method⁴⁰ For the identification of alpha-terpinene in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div><div>1.</div><div>The additive shall be incorporated into the feed in the form of a premixture.</div></div> <div><div>2.</div><div>In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div></div> <div><div>3.</div><div>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."</div></div> <div><div>4.</div><div>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.</div></div> <div><div>5.</div><div>For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div></div>	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

⁴⁰ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b01020	gamma-Terpinene	Additive composition gamma-Terpinene Characterisation of active substance gamma-Terpinene Produced by chemical synthesis or by fractional or steam distillation of essential oils. Purity: min. 95% Chemical formula: C ₁₀ H ₁₆ CAS number: 99-85-4 FLAVIS: 01.020 ----- Analytical method⁴¹ For the identification of gamma-terpinene in the feed additive and in feed flavouring premixtures: <ul style="list-style-type: none">- Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

⁴¹ 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
2b01046	l-Limonene	Additive composition l-Limonene Characterisation of active substance l-Limonene Produced by chemical synthesis or by fractional or steam distillation of essential oils. Purity: min. 95% Chemical formula: C ₁₀ H ₁₆ CAS number: 5989-54-8 FLAVIS: 01.046 ----- Analytical method⁴² For the identification of l-Limonene in the feed additive and in feed flavouring premixtures: - Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	<div>1. The additive shall be incorporated into the feed in the form of a premixture.</div> <div>2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</div> <div>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%: 5 mg."</div> <div>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.</div> <div>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to</div>	<i>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</i>

⁴² 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.

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category: Sensory additives. Functional group: Flavouring compounds								
							address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/982250/2024 CIS
(POOL/G5/2024/982250/982250-EN
CIS.docx)
[...](2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of endo-1,4-beta-mannanase produced with *Thermothelomyces thermophilus* DSM 33149 as a feed additive for all poultry species for fattening and ornamental birds (holder of authorisation: BASF SE)

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the authorisation of a preparation of endo-1,4-beta-mannanase produced by *Thermothelomyces thermophilus* DSM 33149 as a feed additive for all poultry species for fattening and ornamental birds (holder of authorisation: BASF SE)

(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 nutrition¹, 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-mannanase produced by *Thermothelomyces thermophilus* DSM 33149. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of endo-1,4-beta-mannanase produced by *Thermothelomyces thermophilus* DSM 33149 as a feed additive for chickens and turkeys for fattening, minor poultry species for fattening and ornamental birds, requesting that additive to be classified in the category ‘zootechnical additives’ and in the functional group ‘digestibility enhancers’.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 1 February 2023² that the preparation of endo-1,4-beta-mannanase produced by *Thermothelomyces thermophilus* DSM 33149 is safe for the environment and has the potential to be efficacious in chickens for fattening, turkeys for fattening, minor poultry species for fattening and ornamental birds at a use level of 800 TMU/kg. After the assessment of newly submitted data by the applicant, the Authority concluded in its opinion of 30 January 2024³ that the preparation of endo-1,4-beta-mannanase produced by *Thermothelomyces thermophilus* DSM 33149 is safe for the target species at the proposed use level, and for the consumer. The Authority also concluded that the preparation of endo-1,4-beta-mannanase produced by *Thermothelomyces thermophilus* DSM 33149 is not irritant to the eyes or skin. Owing to the proteinaceous nature of the active substance, the additive should be considered a respiratory sensitiser. The

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

² EFSA Journal 2023;21(2):7873.

³ EFSA Journal. 2024;22:e8632..

Authority was not able to conclude on the potential of the additive to be a skin sensitiser. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) In view of the above, the Commission considers that the preparation of endo-1,4-beta-mannanase produced by *Thermothelomyces thermophilus* DSM 33149 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for all poultry species for fattening and ornamental birds. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1
Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Entry into force

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

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed 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
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a47	BASF SE	Endo-1,4-beta-mannanase (EC 3.2.1.78)	<p>Additive composition</p> <p>Preparation of endo-1,4-beta-mannanase (EC 3.2.1.78) produced by <i>Thermothelomyces thermophilus</i> DSM 33149 having a minimum activity of: 8000 TMU ⁽¹⁾/g.</p> <p>Solid form and Liquid form</p> <p>Characterisation of the active substance</p> <p>Endo-1,4-beta-mannanase (EC 3.2.1.78) produced by <i>Thermothelomyces thermophilus</i> DSM 33149</p> <p>Analytical method ⁽²⁾</p> <p>For the determination of the endo-1,4-beta-mannanase activity in the feed additive, premixtures and compound feed:</p> <p>- Enzymatic hydrolysis of</p>	All poultry species for fattening	-	800 TMU	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.	[10 years from the date of entry into force of this Regulation.
				Ornamental birds				2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	To be completed by the Service responsible for the publication]

⁽¹⁾ One Thermostable Mannanase Unit (TMU) is defined as the amount of enzyme that produces reducing carbohydrates having a reducing power corresponding to 1 µM mannose from locust bean gum (0.3 g/100 mL buffer solution) in 1 min at 50°C and pH 3.5.

⁽²⁾ 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.

			dyed carob galactomannan with endo-1,4-beta- mannanase followed by photometry.						
--	--	--	---	--	--	--	--	--	--