COMMISSION IMPLEMENTING REGULATION (EU) 2022/1452

of 1 September 2022

concerning the authorisation of 3-ethylcyclopentan-1,2-dione, 4-hydroxy-2,5-dimethylfuran-3(2H)-one, 4,5-dihydro-2-methylfuran-3(2H)-one, eugenol, 1-methoxy-4-(prop-1(trans)-enyl)benzene, α-pentylcinnamaldehyde, α-hexylcinnamaldehyde and 2-acetylpyridine as feed additives for certain animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) The substances 3-ethylcyclopentan-1,2-dione, 4-hydroxy-2,5-dimethylfuran-3(2H)-one, 4,5-dihydro-2-methylfuran-3(2H)-one, eugenol, 1-methoxy-4-(prop-1(trans)-enyl)benzene, α-pentylcinnamaldehyde, α-hexylcinnamaldehyde and 2-acetylpyridine 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, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, several applications were submitted for the re-evaluation of a preparation of 3-ethylcyclopentan-1,2-dione, α-pentylcinnamaldehyde, α-hexylcinnamaldehyde and 2-acetylpyridine for all animal species, eugenol and 1-methoxy-4-(prop-1(trans)-enyl)benzene for all animal species except poultry and fish and 4-hydroxy-2,5-dimethylfuran-3(2H)-one and 4,5-dihydro-2-methylfuran-3(2H)-one for cats and dogs.

(4) The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The applicant requested the additives to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of flavouring compounds for use in water for drinking. Therefore, the use of these additives in water for drinking should not be allowed.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

(6) The European Food Safety Authority ('the Authority') concluded in its opinions of 15 November 2011 ([3]),13 June 2012 ([4]), 26 January 2016 ([5]), 19 October 2016 ([6]) and 6 December 2016 ([7]), that, under the proposed conditions of use, the additives do not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that hazards for skin and eye contact and respiratory exposure are recognised in regard to those additives. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(7) The Authority concluded that the additives are recognised to flavour food and their function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(8) The assessment of the additives shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation.

(9) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(10) The fact that the additives are not authorised for use as flavourings in water for drinking does not preclude their use in compound feed which is administered via water.

(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 interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(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

Transitional measures

1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 22 March 2023 in accordance with the rules applicable before 22 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing these substances as specified in the Annex which are produced and labelled before 22 September 2023 in accordance with the rules applicable before 22 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

([3]) EFSA Journal 2011;9(12):2440.
([4]) EFSA Journal 2012;10(7):2786.
([5]) EFSA Journal 2016;14(2):4390.
([6]) EFSA Journal 2016;14(11):4618.
([7]) EFSA Journal 2017;15(2):4672.

3. Compound feed and feed materials containing these substances as specified in the Annex which are produced and labelled before 22 September 2024 in accordance with the rules applicable before 22 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Entry into force

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

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

Done at Brussels, 1 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b07057	3-Ethylcyclopentan-1,2-dione	*Additive composition* Preparation of 3-ethylcyclopentan-1,2-dione *Characterisation of active substance* 3-Ethylcyclopentan-1,2-dione Produced by chemical synthesis Purity: > 90 % Chemical formula: $C_7H_{10}O_2$ CAS number: 21835-01-8 FLAVIS: 07.057 *Analytical method* (1) For the identification of the additive in mixtures of flavourings: — Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 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 %: – animals farmed in marine aquaculture systems: 0,05 mg; — cats, dogs and animals farmed in land-based aquaculture systems: 5 mg/kg; — other terrestrial species or categories of animals: 0,5 mg.' 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.	22 September 2032

							5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	

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

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b13010	4-Hydroxy-2,5-dimethylfuran-3 (2H)-one	*Additive composition* 4-Hydroxy-2,5-dimethylfuran-3 (2H)-one *Characterisation of active substance* 4-Hydroxy-2,5-dimethylfuran-3 (2H)-one Produced by chemical synthesis Purity: 98 % Chemical formula: $C_6H_8O_3$ CAS number: 3658-77-3 FLAVIS: 13.010 *Analytical method* (1) For the identification of the additive in mixtures of flavourings: — Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	Cats and dogs	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: — cats and dogs: 5 mg.'	22 September 2032

							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. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	

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

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b13042	4,5-Dihydro-2-methylfuran-3(2H)-one	*Additive composition* 4,5-Dihydro-2-methylfuran-3(2H)-one *Characterisation of active substance* 4,5-Dihydro-2-methylfuran-3(2H)-one	Cats and dogs	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. On the label of the additive the following shall be indicated:	22 September 2032

		Produced by chemical synthesis Purity: 97 % Chemical formula: $C_5H_8O_2$ CAS number: 3188-00-9 FLAVIS: 13.042 *Analytical method* ([1]) For the identification of the additive in mixtures of flavourings: — Gas chromatography mass spectrometry with retention time locking GC-MS-RTL					'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: — cats and dogs: 5 mg.' 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. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	

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

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04003	Eugenol	*Additive composition* Eugenol *Characterisation of active substance* Eugenol Produced by chemical synthesis Purity: > 98 % Chemical formula: $C_{10}H_{12}O_2$ CAS number: 97-53-0 FLAVIS: 04.003	All animal species except poultry and fish	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 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 %: — all animal species except poultry and fish: 25 mg.' 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. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	22 September 2032
		Analytical method [1] For the identification of the additive in mixtures of flavourings: — Gas chromatography mass spectrometry with retention time locking GC-MS-RTL		-	-	-		

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

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b04010	1-Methoxy-4-(prop-1(trans)-enyl)benzene	*Additive composition* 1-Methoxy-4-(prop-1(trans)-enyl)benzene *Characterisation of active substance* 1-Methoxy-4-(prop-1(trans)-enyl)benzene Produced by chemical synthesis Purity: > 99 % Chemical formula: $C_{10}H_{12}O$ CAS number: 4180-23-8 FLAVIS: 04.010 *Analytical method* (1) For the identification of the additive in mixtures of flavourings: — Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	All animal species except poultry and fish	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 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 %: — all animal species except poultry and fish: 25 mg.' 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. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	22 September 2032

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

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b05040	α-Pentylcinnamaldehyde	*Additive composition* α-Pentylcinnamaldehyde *Characterisation of active substance* α-Pentylcinnamaldehyde Produced by chemical synthesis Purity: min. 97 % Chemical formula: $C_{14}H_{18}O$ CAS number: 122-40-7 FLAVIS: 05.040 *Analytical method* ([1]) For the identification of the additive in mixtures of flavourings: — Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 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 %: — animals farmed in marine aquaculture systems: 0,05 mg; — cats: 1 mg/kg; — dogs and animals farmed in land-based aquaculture systems: 5 mg/kg; — other terrestrial species or categories of animals: 0,1 mg.' 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. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks	22 September 2032

							cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	

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

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b05041	α-Hexylcinnamaldehyde	*Additive composition* α-Hexylcinnamaldehyde *Characterisation of active substance* α-Hexylcinnamaldehyde Produced by chemical synthesis Purity: 95 % Chemical formula: $C_{15}H_{20}O$ CAS number: 101-86-0 FLAVIS: 05.041 *Analytical method* ([1]) For the identification of the additive in mixtures of flavourings: — Gas chromatography mass spectrometry with retention time locking GC-MS-RTL	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 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 %: — animals farmed in marine aquaculture systems: 0,05 mg; — cats: 1 mg/kg; — dogs and animals farmed in land-based aquaculture systems: 5 mg/kg; — other terrestrial species or categories of animals: 0,1 mg.'	22 September 2032

							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. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	

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

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b14038	2-Acetylpyridine	*Additive composition* 2-Acetylpyridine *Characterisation of active substance* 2-Acetylpyridine Produced by chemical synthesis	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.	22 September 2032

		Purity: > 97 % Chemical formula: C_7H_7ON CAS number: 1122-62-9 FLAVIS: 14.038 *Analytical method* (1) For the identification of the additive in mixtures of flavourings: — Gas chromatography mass spectrometry with retention time locking GC-MS-RTL					3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: — marine animals: 0,05 mg; — other species or categories of animals: 0,5 mg.' 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. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	

(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