Official Journal of the European Union

L 191

English edition

Legislation

Volume 65

20 July 2022

Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

[1] Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1246

of 14 July 2022

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications 'Bra' (PDO)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]), and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Italy's application for the approval of amendments to the specification for the protected designation of origin 'Bra', registered under Commission Regulation (EC) No 1263/96 ([2]), as amended by Commission Implementing Regulation (EU) No 1280/2014 ([3]).

(2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ([4]) as required by Article 50(2)(a) of that Regulation.

(3) The Commission received two letters opposing the approval of the amendment to the specification for the protected designation of origin 'Bra'. The first letter was received on 4 March 2022 from an association of food ingredients producers established in France. The second letter was received on 15 March 2022 from a natural person resident in France. Both letters were sent directly to the Commission.

(4) In accordance with Article 51(1), second subparagraph, of Regulation (EU) No 1151/2012, natural or legal persons having a legitimate interest, resident or established in a Member State other than that from which the application was submitted, may lodge a notice of opposition with the Member State in which they are established. Taking into consideration that both letters opposing to the approval of the amendment were lodged directly with the Commission and thus not in accordance with the procedure provided in the aforementioned Article 51(1), these letters of opposition are deemed inadmissible.

([1]) OJ L 343, 14.12.2012, p. 1.

([2]) Commission Regulation (EC) No 1263/96 of 1 July 1996 supplementing the Annex to Regulation (EC) No 1107/96 on the registration of geographical indications and designations of origin under the procedure laid down in Article 17 of Regulation (EEC) No 2081/92 (OJ L 163, 2.7.1996, p. 19).

([3]) Commission Implementing Regulation (EU) No 1280/2014 of 26 November 2014 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications [Bra (PDO)] (OJ L 347, 3.12.2014, p. 10).

([4]) OJ C 507, 16.12.2021, p. 18.

(5) In the light of the above, the Commission considers that the amendments to the specification for the protected designation of origin 'Bra' should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the *Official Journal of the European Union* regarding the name 'Bra' (PDO) are hereby approved.

Article 2

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

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

Done at Brussels, 14 July 2022.

For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1247

of 19 July 2022

concerning the authorisation of Allura Red AC as a feed additive for small non-food producing mammals and ornamental birds

(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.

(2) In accordance with Article 7(1) of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of Allura Red AC. 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 Allura Red AC as a feed additive for small non-food producing mammals and ornamental birds, to be classified in the category 'sensory additives' and in the functional group 'colourants'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 November 2021 ([2]) that, under the proposed conditions of use, Allura Red AC does not have adverse effects on animal health, consumer safety or the environment. The Authority could not conclude on the efficacy of Allura Red AC when used in feed for small non-food producing mammals and ornamental birds, considering the wide variety of feedingstuffs used in complete and complementary feed for small non-food producing mammals and ornamental birds, and the uncertainty of which concentration of Allura Red AC would result in a visible effect. However, the Authority also stated that for this additive, which is authorised in food and, where the function for feed is the same as that for food, no further demonstration of efficacy might be necessary. The 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) Moreover, Allura red AC is already authorised in feed for cats and dogs by Commission Implementing Regulation (EU) 2020/197 ([3]) and the Authority concluded, in its opinion of 24 April 2012 ([4]), that Allura Red AC is effective in colouring a typical feed for dogs at a minimum dose of 50 mg/kg, which is similar to the minimum levels proposed by the Authority for this use in small non-food producing mammals and ornamental birds.

(6) In view of the above, the Commission therefore considers that there is sufficient evidence of the efficacy of this substance.

(7) The assessment of Allura Red AC shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2021;19(12):6987.
([3]) Commission Implementing Regulation (EU) 2020/197 of 13 February 2020 concerning the authorisation of allura red AC as a feed additive for cats and dogs (OJ L 42, 14.2.2020, p. 4).
([4]) EFSA Journal 2012;10(5):2675.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants. (i) substances that add or restore colour in feedingstuffs								
2a129	Allura Red AC	*Additive composition:* Allura Red AC described as the sodium salt as the principal component. Solid form (powder or granules)	Guinea pig Chinchilla Degu Hamster Gerbil Chipmunk	-	-	500	1. In the directions for use of the additive and premixtures, the storage conditions and 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 its use. 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, eyes and breathing protection.	9 August 2032
		Characterisation of the active substance: Allura Red AC consists essentially of disodium 2-hydroxy- 1-(2- methoxy-5-methyl-4-sulfonato-phenylazo) naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. The calcium and the potassium salts are also permitted. Produced by chemical synthesis Purity criteria: content not less than 85 % total colouring matters, calculated as the sodium salt (assay) Water insoluble matter: ≤ 0,2 % Subsidiary colouring matters: ≤ 3 % Organic compounds other than colouring matters: — 6-hydroxy-2-naphthalene sulfonic acid, sodium salt: ≤ 0,3 %	Ferrets Other small non-food producing mammals, except dogs and cats	-	-	99		
			Canaries Budgerigars Mynahs Toucans	-	-	45		
			Lovebirds	-	-	51		
			Cockatiels	-	-	79		
			Cockatoos	-	-	115		
			Amazons	-	-	145		
			Parrots	-	-	147		
			Yellow breast macaws	-	-	150		

		— 4-amino-5-methoxy-2- methylbenezene sulfonic acid: ≤ 0,2% — 6,6-oxybis (2-naphthalene sulfonic acid) disodium salt: ≤ 1 % Unsulfonated primary aromatic amines: ≤ 0,01 % (calculated as aniline) Ether extractable matter: ≤ 0,2 % from a solution of pH 7 Chemical formula: $C_{18}H_{14}N_2Na_2O_8S_2$ CAS number: 25956-17-6 EINECS number: 247-368-0	Blue-throated macaws	-	-	173		
			Hyacinth macaws	-	-	214		
			Other ornamental birds	-	-	45		
		Analytical method (1) For the quantification of Allura Red AC in the feed additive: — spectrophotometry at 504 nm (Commission Regulation (EU) No 231/2012 referring to FAO JECFA monographs n. 1 (Vol. 4)) For the quantification of Allura Red AC in feedingstuffs: — high performance liquid chromatography coupled to tandem mass spectrometry (LC- MS/MS)						

(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

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1248

of 19 July 2022

concerning the authorisation of essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. as a feed additive 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) Essential oil from *Origanum vulgare* was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. The additive was subsequently entered in the Register of feed additives as an existing product, 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, an application was submitted for the re-evaluation of essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. for all animal species.

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

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 November 2019 ([3]) that, under the proposed conditions of use, essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. does not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. should be considered as an irritant to skin and eyes, and as a potential skin and respiratory sensitizer. 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.

(6) The Authority also concluded, that essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. is recognised to flavour food and its function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding stuffs (OJ L 270, 14.12.1970, p. 1).
([3]) EFSA Journal 2019;17(12):5909.

(8) The additive concerned contains some components such as carvacrol and thymol for which zootechnical effects have been demonstrated in certain additives already authorised. In order to prevent the use of doses of the additive which could potentially lead to such zootechnical effects, it is necessary to establish a maximum content as a condition of use of essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. as a flavouring in feed.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

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

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

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

Article 2

Transitional measures

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 9 February 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing this substance as specified in the Annex which are produced and labelled before 9 August 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

Article 3

Entry into force

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

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feeding stuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b317-e-o-i	-	Essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw.	*Additive composition:* Essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. *Characterisation of the active substance:* Essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. as defined by the Council of Europe [1]. Carvacrol: ≥ 75 % Thymol: ≤ 2,7 % γ-Terpinene: ≤ 3,8 % *p*-Cymene: ≤ 6,2 % CoE number: 317 CAS number: 336185-21-8 FEMA number: 2660 *Method of analysis* [2] For the determination of carvacrol (phytochemical marker) in the feed additive: — gas chromatography coupled to flame ionisation detection (GC-FID) – ISO 13171.	Chickens for fattening	-	-	22	1. The additive shall be incorporated into feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated. 3. The mixture of essential oil from *Origanum vulgare* L. subsp. *hirtum* (Link) Ietsw. with other authorised additives obtained from *Origanum vulgare* L. shall not be allowed in feeding stuffs. 4. 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, eyes and breathing protection.	9.8.2032
				Laying hens	-	-	33		
				Turkeys for fattening	-	-	30		
				Piglets	-	-	40		
				Pigs for fattening	-	-	48		
				Sows	-	-	63		
				Dairy cows	-	-	57		
				Calves	-	-	100		
				Cattle for fattening, sheep, goats and horses	-	-	88		
				Rabbits	-	-	35		
				Dogs	-	-	106		
				Cats			18		
				Salmonids	-	-	101		
				Ornamental fish	-	-	150		

[1] Natural sources of flavourings – Report No 2 (2007).
[2] Details of the methods of analysis 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

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1249

of 19 July 2022

concerning the authorisation of vitamin B_{12} in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

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

(2) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of vitamin B_{12} in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 as a feed additive for all animal species, requesting the additive to be classified in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 June 2018 ([3]) and 18 November 2020 ([4]) that, under the proposed conditions of use, vitamin B_{12} in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that due to its high endotoxin content, potential inhalation exposure when handling premixtures and its reported irritancy to skin and eyes, vitamin B12 in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 is considered to pose a risk to user health. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(4) The assessment of vitamin B_{12} in the form of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 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 additive should be authorised.

(5) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substance concerned, it is appropriate to allow a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

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

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding stuffs (OJ L 270, 14.12.1970, p. 1).
([3]) EFSA Journal 2018;16(7):5336.
([4]) EFSA Journal 2020;18(12):6335.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance 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

Transitional measures

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 9 February 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 9 August 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 9 August 2024 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 3

Entry into force

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

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

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 feeding stuff with a moisture content of 12 %			
Category of nutritional additives **Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect**								
3a835	'Vitamin B_{12}' or 'cyanocobalamin'	*Additive composition* Preparation of cyanocobalamin produced by *Ensifer adhaerens* CNCM I-5541 containing ≤ 1 % of cyanocobalamin Solid form *Characterisation of active substance* Cyanocobalamin $C_{63}H_{88}CoN_{14}O_{14}P$ CAS number: 68-19-9 Purity: ≥ 96 % *Analytical method* (1) For the quantification of Vitamin B_{12}/cyanocobalamin in the feed additive preparation and feeding stuffs: — 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 and 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 its use. 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, eyes and breathing protection. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air (2).	9 August 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

(2) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2018;16(7):5336).

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1250

of 19 July 2022

concerning the authorisation of ethyl acrylate, pentyl isovalerate, butyl 2-methyl butyrate, 2-methylundecanal, (2*E*)-methylcrotonic acid, ethyl (*E*,*Z*)-deca-2,4-dienoate, butan-2-one, cyclohexyl acetate, 3,4-dimethylcyclopentan-1,2-dione, 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one, phenethyl butyrate, hexyl phenylacetate, 4-methylacetophenone, 4-methoxyacetophenone, 3-methylphenol, 3,4-dimethylphenol, 1-methoxy-4-methylbenzene, trimethyloxazole and 4,5-dihydrothiophen-3 (2H)-one as feed additives for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

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

(2) The substances ethyl acrylate, pentyl isovalerate, butyl 2-methyl butyrate, 2-methylundecanal, (2*E*)-methylcrotonic acid, ethyl (*E*,*Z*)-deca-2,4-dienoate, butan-2-one, cyclohexyl acetate, 3,4-dimethylcyclopentan-1,2-dione, 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one, phenethyl butyrate, hexyl phenylacetate, 4-methylacetophenone, 4-methoxyacetophenone, 3-methylphenol, 3,4-dimethylphenol, 1-methoxy-4-methylbenzene, trimethyloxazole and 4,5-dihydrothiophen-3(2H)-one were authorised without a time limit in accordance with Directive 70/524/EEC as a feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, several applications were submitted for the re-evaluation of those additives for all animal species.

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

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

([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 1 February 2012 ([3]), 7 March 2012 ([4]), 25 April 2012 ([5]), 17 October 2012 ([6]), 12 March 2013 ([7]), 5 March 2014 ([8]), 20 October 2015 ([9]), 26 January 2016 ([10]), 8 March 2016 ([11]), 20 April 2016 ([12]), 25 May 2016 ([13]), 12 July 2016 ([14]) and 19 October 2016 ([15]), that, under the proposed conditions of use, the additives do not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that the additives should be considered as irritants to skin, eyes and respiratory tract and as skin sensitizers. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

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

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

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

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

(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 allow 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.

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

Article 2

Transitional measures

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

2. Compound feed and feed materials containing these substances as specified in the Annex which are produced and labelled before 9 August 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing these substances as specified in the Annex which are produced and labelled before 9 August 2024 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Entry into force

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

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

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**								
2b09037	Ethyl acrylate	*Additive composition* Ethyl acrylate *Characterisation of active substance* Ethyl acrylate Produced by chemical synthesis Purity: 97 % Chemical formula: $C_5H_8O_2$ CAS number: 140-88-5 FLAVIS: 09.037 *Analytical method* (1) For the identification of ethyl acrylate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — pigs and poultry: 1 mg; — other species or categories of animals: 1,5 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.	9 August 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**								
2b09499	Pentyl isovalerate	*Additive composition* Pentyl isovalerate *Characterisation of active substance* Pentyl isovalerate Produced by chemical synthesis Purity: 98 % Chemical formula: $C_{10}H_{20}O_2$ CAS number: 25415-62-7 FLAVIS: 09.499 *Analytical method* (1) For the identification of pentyl isovalerate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — pigs and poultry: 1 mg; — other species or categories of animals: 1,5 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.	9 August 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**								
2b09519	Butyl 2-methyl butyrate	*Additive composition* Butyl 2-methyl butyrate *Characterisation of active substance* Butyl 2-methyl butyrate Produced by chemical synthesis Purity: 95 % Chemical formula: $C_9H_{18}O_2$ CAS number: 15706-73-7 FLAVIS: 09.519 *Analytical method* (1) For the identification of butyl 2-methyl butyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — pigs and poultry: 1 mg; — other species or categories of animals: 1,5 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.	9 August 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**								
2b05077	2-Methylundecanal	*Additive composition* 2-Methylundecanal *Characterisation of active substance* 2-Methylundecanal Produced by chemical synthesis Purity: 97 % Chemical formula: $C_{12}H_{24}O$ CAS number: 110-41-8 FLAVIS: 05.077	All animal species	-	-	-	1. The additive shall 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 %: — pigs and poultry: 1 mg; — other species or categories of animals: 1,5 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.	9 August 2032
		Analytical method ([1]) For the identification of 2-methylundecanal in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.		-	-	-		

([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**								
2b08064	(*2E*)-Methylcrotonic acid	*Additive composition* (*2E*)-Methylcrotonic acid *Characterisation of active substance* (*2E*)-Methylcrotonic acid Produced by chemical synthesis Purity: min. 99 % Chemical formula: $C_5H_8O_2$ CAS number: 80-59-1 FLAVIS: 08.064 *Analytical method* (1) For the identification of (*2E*)-methylcrotonic acid in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — marine animals: 0,05 mg; — other species or categories of animals: 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 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.	9 August 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**								
2b09260	Ethyl (*E,Z*)-dec-a-2,4-dieno-ate	*Additive composition* Ethyl (*E,Z*)-deca-2,4-dienoate *Characterisation of active substance* Ethyl (*E,Z*)-deca-2,4-dienoate Produced by chemical synthesis Purity: min. 90 % Chemical formula: $C_{12}H_{20}O_2$ CAS number: 3025-30-7 FLAVIS: 09.260 *Analytical method* (1) For the identification of ethyl (EZ)-deca-2,4-dienoate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage 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 %: — marine animals: 0,05 mg; — other species or categories of animals: 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 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.	9 August 2032

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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**								
2b07053	Butan-2-one	*Additive composition* Butan-2-one *Characterisation of active substance* Butan-2-one Produced by chemical synthesis Purity: min. 99,5 % Chemical formula: C_4H_8O CAS number: 78-93-3 FLAVIS: 07.053 *Analytical method* (1) For the identification of butan-2-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — pigs and poultry: 1 mg; — other species or categories of animals: 1,5 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.	9 August 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**								
2b09027	Cyclohexyl acetate	*Additive composition* Cyclohexyl acetate *Characterisation of active substance* Cyclohexyl acetate Produced by chemical synthesis Purity: > 98 % Chemical formula: $C_8H_{14}O_2$ CAS number: 622-45-7 FLAVIS: 09.027 *Analytical method* (1) For the identification of cyclohexyl acetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage 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 %: — marine animals: 0,05 mg; — other species or categories of animals: 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 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.	9 August 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**								
2b07075	3,4-Dimethylcyclopentan-1,2-dione	*Additive composition* 3,4-Dimethylcyclopentan-1,2-dione *Characterisation of active substance* 3,4-Dimethylcyclopentan-1,2-dione Produced by chemical synthesis Purity: > 98 % Chemical formula: $C_7H_{10}O_2$ CAS number: 13494-06-9 FLAVIS: 07.075 *Analytical method* (1) For the identification of 3,4-dimethylcyclopentan-1,2-dione in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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; — 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.	9 August 2032

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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**								
2b10023	5-Ethyl-3-hydroxy-4-methyl-furan-2 (5H)-one	*Additive composition* 5-Ethyl-3-hydroxy-4-methylfuran-2(5H)-one *Characterisation of active substance* 5-Ethyl-3-hydroxy-4-methylfuran-2(5H)-one Produced by chemical synthesis Purity: 95 % Chemical formula: $C_7H_{10}O_3$ CAS number: 698–10–2 FLAVIS: 10.023 *Analytical method* (1) For the identification of 5-ethyl-3-hydroxy-4-methylfuran-2(5H)-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — marine animals: 0,05 mg; — poultry and pigs: 0,05 mg; — other species or categories of animals: 0,08 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.	9 August 2032

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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**								
2b09168	Phenethyl butyrate	*Additive composition* Phenethyl butyrate *Characterisation of active substance* Phenethyl butyrate Produced by chemical synthesis Purity: 97 % Chemical formula: $C_{12}H_{16}O_2$ CAS number: 103-52-6 FLAVIS: 09.168	All animal species	-	-	-	1. The additive shall 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 %: — pigs and poultry: 1 mg; — other species or categories of animals: 1,5 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.	9 August 2032
		Analytical method ([1]) For the identification of phenethyl butyrate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.		-	-	-		

([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**								
2b09804	Hexyl phenylacetate	*Additive composition* Hexyl phenylacetate *Characterisation of active substance* Hexyl phenylacetate Produced by chemical synthesis Purity: 97 % Chemical formula: $C_{14}H_{20}O_2$ CAS number: 5421-17-0 FLAVIS: 09.804	All animal species	-	-	-	1. The additive shall 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 %: — pigs and poultry: 1 mg; — other species or categories of animals: 1,5 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.	9 August 2032
		Analytical method ([1]) For the identification of hexyl phenylacetate in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.		-	-	-		

([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**								
2b07022	4-Methylacetophenone	*Additive composition* 4-Methylacetophenone *Characterisation of active substance* 4-Methylacetophenone Produced by chemical synthesis Purity: > 95 % Chemical formula: $C_9H_{10}O$ CAS number: 122-00-9 FLAVIS: 07.022 *Analytical method* (1) For the identification of 4-methylacetophenone in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — marine animals: 0,05 mg; — cats: 1 mg; — other species or categories of animals: 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.	9 August 2032

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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**								
2b07038	4-Methoxyacetophenone	*Additive composition* 4-Methoxyacetophenone *Characterisation of active substance* 4-Methoxyacetophenone Produced by chemical synthesis Purity: > 97 % Chemical formula: $C_9H_{10}O_2$ CAS number: 100-06-1 FLAVIS: 07.038 *Analytical method* (1) For the identification of 4-methoxyacetophenone in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — marine animals: 0,05 mg; — cats: 1 mg; — other species or categories of animals: 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.	9 August 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**								
2b04026	3-Methyl-phenol	*Additive composition* 3-Methylphenol *Characterisation of active substance* 3-Methylphenol Produced by chemical synthesis Purity: 98 % Chemical formula: C_7H_8O CAS number: 108-39-4 FLAVIS: 04.026 *Analytical method* (1) For the identification of 3-methylphenol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: 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.	9 August 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**								
2b04048	3,4-Dimethylphenol	*Additive composition* 3,4-Dimethylphenol *Characterisation of active substance* 3,4-Dimethylphenol Produced by chemical synthesis Purity: 98 % Chemical formula: $C_8H_{10}O$ CAS number: 95-65-8 FLAVIS: 04.048 *Analytical method* (1) For the identification of 3,4-dimethylphenol in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: 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.	9 August 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**								
2b04015	1-Methoxy-4-methyl-benzene	*Additive composition* 1-Methoxy-4-methylbenzene *Characterisation of active substance* 1-Methoxy-4-methylbenzene Produced by chemical synthesis Purity: 99 % Chemical formula: $C_8H_{10}O$ CAS number: 104-93-8 FLAVIS: 04.015 *Analytical method* (1) For the identification of 1-methoxy-4-methylbenzene in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: 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 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.	9 August 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**								
2b13169	Trimethyloxazole	*Additive composition* Trimethyloxazole *Characterisation of active substance* Trimethyloxazole Produced by chemical synthesis Purity: > 95 % Chemical formula: C_6H_9ON CAS number: 20662-84-4 FLAVIS: 13.169 *Analytical method* (1) For the identification of trimethyloxazole in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: — marine animals: 0,05 mg; — poultry and pigs: 0,3 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.	9 August 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**								
2b15012	4,5-Dihydrothiophen-3(2H)-one	*Additive composition* 4,5-Dihydrothiophen-3(2H)-one *Characterisation of active substance* 4,5-Dihydrothiophen-3(2H)-one Produced by chemical synthesis. Purity: 97 % Chemical formula: C_4H_6OS CAS number: 1003-04-9 FLAVIS: 15.012 *Analytical method* (1) For the identification of 4,5-dihydrothiophen-3(2H)-one in the feed additive and in feed flavouring premixtures: Gas chromatography mass spectrometry with retention time locking GC-MS-RTL.	All animal species	-	-	-	1. The additive shall 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 %: 0,05 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.	9 August 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

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1251

of 19 July 2022

renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances, and Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 20(1) in conjunction with Article 22(1) thereof,

Whereas:

(1) Commission Directive 2008/127/EC ([2]) included Straight Chain Lepidopteran Pheromones as active substances in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substances Straight Chain Lepidopteran Pheromones, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 August 2022.

(4) Straight Chain Lepidopteran Pheromones are substances which are naturally produced by insects of the order of Lepidoptera. They share a common structural definition and mechanism of action and can be composed of acetates, aldehydes or alcohols.

(5) Applications for the renewal of the approval of the active substances Straight Chain Lepidopteran Pheromones were submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(6) Applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(7) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 3 June 2019.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([5]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(8) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(9) On 19 May 2021, the Authority communicated to the Commission its conclusion ([6]) on whether Straight Chain Lepidopteran Pheromones can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority's conclusion differentiated between acetates, aldehydes and alcohols within the Straight Chain Lepidopteran Pheromones.

(10) The Commission presented its renewal report and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on the 1 December 2021 and 30 March 2022 respectively.

(11) The Commission invited the applicants to submit their comments on the conclusion of the Authority and, in accordance with Article 14(1), third paragraph, of Implementing Regulation (EU) No 844/2012 ([7]), on the renewal report. The applicants submitted their comments, which have been carefully examined.

(12) The Commission considers that it has been established with respect to one or more representative uses of at least one plant protection product containing the active substances Straight Chain Lepidopteran Pheromones (acetates, aldehydes or alcohols) that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(13) The Commission further considers that Straight Chain Lepidopteran Pheromones (acetates) are low-risk active substances pursuant to Article 22 of Regulation (EC) No 1107/2009, as they are not substances of concern and fulfil the conditions set in point 5 of Annex II to that Regulation.

(14) It is therefore appropriate to renew the approval of Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances and the approval of Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) as active substances.

(15) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to provide for certain conditions.

(16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(17) This Regulation should apply from the day after the date of expiry of the approval of Straight Chain Lepidopteran Pheromones (acetates), Straight Chain Lepidopteran Pheromones (aldehydes and alcohols).

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

([6]) EFSA (European Food Safety Authority), Conclusion on the peer review of the pesticide risk assessment of the active substance Straight Chain Lepidopteran Pheromones (SCLPs). *EFSA Journal* 2021;19(6):6656, 24 pp. doi:10.2903/j.efsa.2021,6656. Available online: http://www.efsa.europa.eu

([7]) This Regulation was replaced by Regulation (EU) 2020/1740, however, it shall continue to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substances Straight Chain Lepidopteran Pheromones (acetates), Straight Chain Lepidopteran Pheromones (aldehydes) and Straight Chain Lepidopteran Pheromones (alcohols) is renewed, subject to conditions set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

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

It shall apply from 1 September 2022.

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
Straight Chain Lepidopteran Pheromones (acetates)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	*1 September 2022*	*30 August 2037*	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.
Straight Chain Lepidopteran Pheromones (aldehydes)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	*1 September 2022*	*30 August 2037*	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.
Straight Chain Lepidopteran Pheromones (alcohols)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	*1 September 2022*	*30 August 2037*	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 255 on Straight Chain Lepidopteran Pheromones is deleted;

(2) in Part B, the following entries are added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'153	Straight Chain Lepidopteran Pheromones (aldehydes)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	*1 September 2022*	*30 August 2037*	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.'
'154	Straight Chain Lepidopteran Pheromones (alcohols)	Review Report SANTE SANTE/ 10828/2021	Review Report SANTE SANTE/ 10828/2021	*1 September 2022*	*30 August 2037*	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.'

(3) in Part D, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'38	Straight Chain Lepidopteran Pheromones (acetates)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	*1 September 2022*	*30 August 2037*	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.'

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1252

of 19 July 2022

amending Implementing Regulation (EU) 2015/408 to update the list of candidates for substitution

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Articles 78(2) thereof,

Whereas:

(1) The Annex to Commission Implementing Regulation (EU) 2015/408 ([2]) contains a list of active substances which satisfy the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009 for being considered as candidates for substitution.

(2) A number of those substances are no longer approved or their approvals have been renewed pursuant to Article 20 of Regulation (EC) No 1107/2009, resulting in a listing in Part E of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]). Their listing in the Annex to Implementing Regulation (EU) 2015/408 is no longer relevant. In the interest of clarity and transparency, they should be deleted from this Annex.

(3) Quizalofop-P (variant quizalofop-P-tefuryl) is an approved active substance listed in the Annex to Implementing Regulation (EU) 2015/408 as a candidate for substitution because of its former harmonised classification as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]). Commission Regulation (EU) 2018/1480 ([5]) updated this classification to toxic for reproduction category 2. Therefore, quizalofop-P-tefuryl no longer fulfils the criteria to be considered a candidate for substitution and should be deleted from the Annex to Implementing Regulation (EU) 2015/408.

(4) Implementing Regulation (EU) 2015/408 should therefore be amended accordingly.

(5) 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

The Annex to Implementing Regulation (EU) 2015/408 is amended in accordance with the Annex to this Regulation.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ L 67, 12.3.2015, p. 18).

([3]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([4]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([5]) Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).

Article 2

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

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) 2015/408 the following entries are deleted:

amitrole;

bifenthrin;

bromadiolone;

carbendazim;

carbetamide;

copper compounds (variants copper hydroxide, copper oxychloride, copper oxide, Bordeaux mixture and tribasic copper sulphate);

cyproconazole;

difenacoum;

dimethoate;

diquat;

epoxiconazole;

esfenvalerate;

ethoprophos;

etoxazole;

famoxadone;

fenamiphos;

fenbutatin oxide;

fipronil;

fluquinconazole;

glufosinate;

haloxyfop-P;

imazamox;

imazosulfuron;

isoproturon;

isopyrazam;

lambda-cyhalothrin;

linuron;

lufenuron;

mecoprop;

methomyl;

metsulfuron-methyl;

molinate;

myclobutanil;

oxadiargyl;

oxadiazon;

pendimethalin;

prochloraz;

profoxydim;

propiconazole;

prosulfuron;

quinoxyfen;

quizalofop-P (variant quizalofop-P-tefuryl);

tepraloxydim;

thiacloprid;

triasulfuron;

triazoxide;

warfarin.

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1253

of 19 July 2022

correcting Regulation (EU) No 748/2012 as regards derogations from certain requirements introduced by Delegated Regulation (EU) 2022/201

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ([1]), and in particular Article 62(14) thereof,

Whereas:

(1) Commission Regulation (EU) No 748/2012 ([2]) lays down common technical requirements for the design and production of civil aircraft, as well as engines, propellers and parts to be installed therein.

(2) In accordance with point 3.1(b) of Annex II to Regulation (EU) 2018/1139, approved design and production organisations are to implement and maintain a management system to ensure compliance with the essential requirements set out in that Annex, manage safety risks and aim for the continuous improvement of that system.

(3) Pursuant to Annex 19 to the Convention on International Civil Aviation, signed in Chicago on 7 December 1944 ('the Chicago Convention'), competent authorities are to require approved design and production organisations to implement a safety management system.

(4) Commission Delegated Regulation (EU) 2022/201 ([3]) introduced a management system for all approved design and production organisations falling within the scope of Annex I to Regulation (EU) No 748/2012 in order to comply with the International Civil Aviation Organisation ('ICAO') International Standards and Recommended Practices established in Annex 19 to the Chicago Convention.

(5) Commission Implementing Regulation (EU) 2022/203 ([4]) introduced a management system and occurrence-reporting systems to be established by competent authorities.

(6) Delegated Regulation (EU) 2022/201 and Implementing Regulation (EU) 2022/203 amended, respectively, Article 8 and Article 9 of Regulation (EU) No 748/2012. The amendments provided for transitional periods until 7 March 2025 for design organisations and production organisations to correct any finding of non-compliance related to the requirements that were introduced by Delegated Regulation (EU) 2022/201 in Annex I to Regulation (EU) No 748/2012.

(7) The adopted text amending Article 9 of Regulation (EU) No 748/2012, wrongly referred to Implementing Regulation (EU) 2022/203, instead of referring to Delegated Regulation (EU) 2022/201.

([1]) OJ L 212, 22.8.2018, p. 1.

([2]) Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1).

([3]) Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation (OJ L 33, 15.2.2022, p. 7).

([4]) Commission Implementing Regulation (EU) 2022/203 of 14 February 2022 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by competent authorities, and correcting Regulation (EU) No 748/2012 as regards the issuance of airworthiness review certificates (OJ L 33, 15.2.2022, p. 46).

(8) In addition, the text amending Article 9 of Regulation (EU) No 748/2012 did not take into account the fact that only a limited set of the requirements introduced with Delegated Regulation (EU) 2022/201, mainly the requirements on reporting and record keeping, are applicable to organisations that produce products, parts or appliances without an approval certificate holding a letter of agreement (LoA) and that that LoA is valid only for a limited period. The transitional period until 7 March 2025 to correct findings of non-compliance related to the requirements that were introduced by Delegated Regulation (EU) 2022/201 is therefore not relevant for those organisations. Thus, in order to ensure consistency with the applicability date of Delegated Regulation (EU) 2022/201, organisations for which the LoA is issued on or before 7 March 2023, should not be required to comply with the requirements introduced by Delegated Regulation (EU) 2022/201.

(9) Regulation (EU) No 748/2012 should therefore be corrected accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the committee established in accordance with Article 127(1) of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 9 of Regulation (EU) No 748/2012, paragraphs 5 and 6 are replaced by the following:

'5. By way of derogation from points 21.B.225(d)(1) and (2) of Annex I (Part 21), a production organisation that holds a valid approval certificate issued in accordance with Annex I (Part 21) may correct, until 7 March 2025, any findings of non-compliance related to the Annex I requirements introduced by Commission Delegated Regulation (EU) 2022/201 (*).

Where after 7 March 2025 the organisation has not closed those findings, the approval certificate shall be revoked, limited or suspended in whole or in part.

6. By way of derogation from point 21.A.125C(a)(1) of Annex I (Part 21), an organisation that produces products, parts or appliances without an approval certificate and that holds a valid letter of agreement issued on or before 7 March 2023 in accordance with Annex I (Part 21) shall not be required to comply with the relevant Annex I requirements introduced by Delegated Regulation (EU) 2022/201.

(*) Commission Delegated Regulation (EU) 2022/201 of 10 December 2021 amending Regulation (EU) No 748/2012 as regards management systems and occurrence-reporting systems to be established by design and production organisations, as well as procedures applied by the Agency, and correcting that Regulation (OJ L 33, 15.2.2022, p. 7).'.

Article 2

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

It shall apply from 7 March 2023.

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1254

of 19 July 2022

amending Regulation (EU) 2015/640 as regards the introduction of new additional airworthiness requirements

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ([1]), and in particular Article 17(1), point (h), thereof,

Whereas:

(1) Pursuant to Article 76(3) of Regulation (EU) 2018/1139, the European Union Aviation Safety Agency (the 'Agency') issues certification specifications (CSs) and regularly updates them in order to ensure that CSs remain fit for purpose. However, an aircraft the design of which has already been certified is not required to comply with the updated version of the applicable CSs when it is produced or while in service. In order to support continuing airworthiness and safety improvements, compliance of such aircraft with additional airworthiness requirements that were not included in the initial CSs at the time of certification of the design should be introduced. Commission Regulation (EU) 2015/640 ([2]) sets out such additional airworthiness requirements.

(2) With effect from 26 August 2023, Commission Implementing Regulation (EU) 2020/1159 ([3]) inserted in Annex I (Part-26) to Regulation (EU) 2015/640 a new point 26.157. In accordance with that provision, all in-service large aeroplanes certified by the Agency and used in commercial air transport on or after 26 August 2023 are to comply with additional airworthiness requirements for the conversion of Class D cargo or baggage compartments. However, further analysis has shown that for certain type of operations, including primarily business operations, certain large, low-occupancy aeroplanes present lower risk of an in-flight fire starting in their Class D cargo or baggage compartment and developing into an uncontrollable fire. In order to avoid imposing non-proportionate and non-cost-efficient burdens on their operators, the operators of those aeroplane types should therefore be exempted from the obligation to comply with point 26.157.

(3) With effect from 22 June 2021, the Agency amended the Certification Specifications for Large Aeroplanes (CS-25) to introduce a new specification that requires the establishment of means to minimise the risk of a tyre being below its minimum serviceable inflation pressure during operation. However, that new specification applies only to large aeroplanes for which application for the approval of the design was made after 22 June 2021. Considering that certain large aeroplanes might not comply with that new specification, additional airworthiness requirements should be introduced. Having due regard to the nature and risk of operations with large aeroplanes while maintaining a high uniform level of civil aviation safety in the Union, it is proportionate and cost-efficient to introduce those additional airworthiness requirements for all large aeroplanes in-service that were produced on the basis of a design already certified by the Agency.

([1]) OJ L 212, 22.8.2018, p. 1.

([2]) Commission Regulation (EU) 2015/640 of 23 April 2015 on additional airworthiness specifications for a given type of operations and amending Regulation (EU) No 965/2012 (OJ L 106, 24.4.2015, p. 18).

([3]) Commission Implementing Regulation (EU) 2020/1159 of 5 August 2020 amending Regulations (EU) No 1321/2014 and (EU) No 2015/640 as regards the introduction of new additional airworthiness requirements (OJ L 257, 6.8.2020, p. 14).

(4) The Agency has amended the Certification Specifications for Small Rotorcraft (CS-27) and Large Rotorcraft (CS-29) respectively to introduce new specifications for rotorcraft intended for use in offshore operations. In accordance with the new specifications, the rotorcraft are required to be certified for ditching or are required to have emergency flotation systems installed on them. Having due regard to the nature and risk of helicopter offshore operations and the need to maintain a high uniform level of civil aviation safety in the Union, it is proportionate and cost-efficient to render some of those specifications applicable to existing helicopters operated in the Union and to those that will be produced after the entry into force of this Regulation on the basis of a design which has already been certified by the Agency.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 127 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2015/640 is amended as follows:

(1) in Article 2 of Regulation (EU) 2015/640, the following points (ca), (cb) and (cc) are inserted:

'(ca) "small helicopter" means a helicopter that has the Certification Specifications for Small Rotorcraft (CS-27) or equivalent in its certification basis;

(cb) "small category A helicopter" means a small helicopter that has all the characteristics of category A as defined in point (17) of Annex I to Regulation (EU) No 965/2012 and has in its certification basis the additional specifications set out in the Certification Specifications for Large Rotorcraft (CS-29) that are applicable by virtue of the reference in Appendix C to CS-27, or equivalent;

(cc) "Substantiated sea conditions" means those sea conditions which were selected by the applicant for a type certificate or supplemental type certificate against which the resistance of the rotorcraft to capsize has been demonstrated and subsequently certified for ditching or emergency flotation provisions.';

(2) Annex I (Part-26) is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 9 September 2022, except for:

(a) points 2 and 6 of the Annex, which shall apply from 26 August 2023;

(b) point 4 and point 5 of the Annex as regards the addition of points 26.410, 26.415, points 26.420(a) and (b), and point 26.425 of Annex I (Part-26) to Regulation (EU) 2015/640, which shall apply from 9 August 2023;

(c) point 5 of the Annex as regards the addition of point 26.420(c) and point 26.435(a) of Annex I (Part-26) to Regulation (EU) 2015/640, which shall apply from 9 August 2024;

(d) point 5 of the Annex as regards the addition of point 26.435(b) of Annex I (Part-26) to Regulation (EU) 2015/640, which shall apply from 9 August 2026.

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex I to Regulation (EU) 2015/640 (Part-26) is amended as follows:

(1) the table of contents is replaced by the following:

'CONTENTS

26.308 Damage tolerance data for existing repairs to fatigue critical structure

26.309 Repair evaluation guidelines

26.330 Damage tolerance data for existing supplemental type-certificates (STCs), other existing major changes and existing repairs affecting those changes or STCs

26.331 Compliance Plan for STC holders

26.332 Identification of changes affecting fatigue critical structure

26.333 Damage tolerance data for STCs and repairs to those STCs approved on or after 1 September 2003

26.334 Damage tolerance data for STCs and other changes and repairs to those changes approved before 1 September 2003

26.370 Continuing airworthiness tasks and aircraft maintenance programme

SUBPART C – HELICOPTERS

26.400 Fire extinguishers

26.410 Emergency controls operated underwater

26.415 Underwater emergency exits

26.420 Emergency equipment for flight over water

26.425 Provision of substantiated sea conditions

26.430 Resistance of an emergency flotation system to damage

26.431 Determination of the robustness of emergency flotation system designs

26.435 Automatic deployment of an emergency flotation system

Appendix 1 – List of aeroplane models not subject to certain provisions of Annex I (Part-26)';

(2) point 26.157 is replaced by the following:

'26.157 **Conversion of Class D compartments**

Operators of large aeroplanes used in commercial air transport, type certified on or after 1 January 1958, except for operators of an aeroplane model listed in Table A.1 of Appendix 1 to this Annex, shall ensure that:

(a) for aeroplanes, the operation of which involves the transport of passengers, each Class D cargo or baggage compartment, regardless of its volume, complies with the certification specifications applicable to a Class C compartment;

(b) for aeroplanes, the operation of which involves the transport of cargo only, each Class D cargo compartment, regardless of its volume, complies with the certification specifications applicable to either a Class C or a Class E compartment.';

(3) the following point 26.201 is inserted:

'26.201 **Tyre inflation pressure**

Operators of large aeroplanes shall minimise the risk of a tyre being below its minimum serviceable inflation pressure during operation.';

(4) the title of Subpart C is replaced by the following:

'SUBPART C – HELICOPTERS';

(5) the following points 26.410, 26.415, 26.420, 26.425, 26.430, 26.431 and 26.435 are added:

'26.410 **Emergency controls operated underwater**

Operators of small helicopters and large helicopters that are required, in accordance with point CAT.IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be designed for landing on water or certified for ditching, shall ensure that all the emergency controls that need to be operated underwater are marked with the method of operation as well as with yellow and black stripes.

26.415 **Underwater emergency exits**

(a) Operators of small helicopters and large helicopters that are required, in accordance with point CAT.IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be designed for landing on water or certified for ditching, shall ensure that:

(1) it is possible for occupants to easily identify the means to operate all the underwater emergency exits to facilitate egress in the case of ditching or capsize;

(2) an underwater emergency exit is available on each side of the helicopter for each unit, (or part of a unit, of four passenger seats unless the emergency underwater exit is large enough to permit the simultaneous egress of two passengers;

(3) passenger seats are located in relation to the underwater emergency exits referred to in point (2) in such a way as to facilitate the escape of passengers in the event of the helicopter capsizing and the cabin becoming flooded.

(b) Operators of small category A helicopters and large helicopters that are required, in accordance with point CAT. IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be designed for landing on water or certified for ditching, shall ensure that:

(1) all emergency exits, including flight crew emergency exits, and any door, window or other opening suitable to be used for the purpose of underwater escape, remain operable in an emergency;

(2) an automatic means is provided to easily identify the periphery of the apertures of all underwater emergency exits in all lighting conditions; such markings must be designed to remain visible in case the helicopter is capsized or the cabin is submerged.

26.420 **Emergency equipment for flight over water**

(a) Operators of small helicopters and large helicopters that are required to comply with the requirements of point CAT.IDE.H.300 of Annex IV, point NCC.IDE.H.227 of Annex VI or point SPO.IDE.H.199 of Annex VIII to Regulation (EU) No 965/2012, shall ensure that each inflated life raft has a means to hold it near the helicopter, and an additional means to keep the inflated life raft attached to the helicopter further away at a distance that would not pose a danger to the life raft itself nor to the persons on board. In the event that the helicopter totally submerges, both of those life raft retention means shall break before the helicopter submerges, even when the life raft is empty.

(b) Operators of small helicopters and large helicopters that are required, in accordance with point CAT.IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be designed for landing on water or certified for ditching, shall ensure that stowage provisions are provided that accommodate one life preserver for each helicopter occupant within easy reach of each occupant while seated, unless occupants are always required to wear them whilst on board the helicopter.

(c) Operators of large helicopters that are required by point SPA.HOFO.165(d) of Annex V to Regulation (EU) No 965/2012 to have one or more life rafts installed, shall ensure that the life raft(s):

(1) is (are) remotely deployable, with the means to deploy the life raft(s), located within easy reach of the flight crew, the occupants of the passenger cabin and any survivors in the water, with the helicopter in an upright floating or capsized position;

(2) can be reliably deployed with the helicopter in any reasonably foreseeable floating attitude, including capsize, and in the substantiated sea conditions for capsize resistance.

26.425 **Provision of substantiated sea conditions**

(a) A holder of a type certificate for a small helicopter or a large helicopter shall ensure that the substantiated sea conditions for capsize resistance and any associated information relating to the ditching certification or emergency flotation provisions are included in the rotorcraft flight manual (RFM) and provided to all operators.

(b) A holder of a supplemental type certificate for an emergency flotation system that is installed on a small helicopter or a large helicopter shall ensure that the substantiated sea conditions for capsize resistance and any associated information relating to the ditching certification or emergency flotation provisions are included in the RFM and provided to all operators.

26.430 **Resistance of an emergency flotation system to damage**

(a) Operators of small helicopters or large helicopters that have their first individual certificate of airworthiness issued on or after 9 August 2025 and that are required, in accordance with point CAT.IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be designed for landing on water or certified for ditching, shall ensure that if the helicopter includes a stowed emergency flotation system, the effects on the successful deployment and retention of the emergency flotation system as a result of possible damage from a water impact are minimised as far as practicable in the design.

(b) Operators of small helicopters or large helicopters with stowed emergency flotation systems that are installed for the first time on or after 9 August 2025 that are required, in accordance with CAT.IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be certified for ditching, shall ensure that the effects on the successful deployment and retention of the emergency flotation systems as a result of possible damage from a water impact are minimised as far as practicable in the design.

26.431 **Determination of the robustness of emergency flotation system designs**

(a) An operator of a small helicopter or a large helicopter that is required, in accordance with point CAT.IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be designed for landing on water or certified for ditching, may request the person referred to in point (b) to provide the services referred to in point (c), where both the following conditions are met:

(1) the operator is required to demonstrate compliance with point 26.430 of this Annex;

(2) the robustness of the emergency flotation system in the event of water impact has not been demonstrated as part of the type certificate or supplemental type certificate of that helicopter.

(b) The person who shall provide the services referred to in point (c) are:

(1) the type certificate holder, if the emergency flotation system is included within the type design;

(2) the supplemental type certificate holder, if the emergency flotation system is certified through a supplemental type certificate.

(c) The person referred to in point (b) shall:

(1) determine that the effects on the successful deployment and retention of the emergency flotation system as a result of possible damage from a water impact are minimised, as far as practicable;

(2) determine that the effects referred to in point (c)(1) are taken into consideration in the design of the emergency flotation system;

(3) provide an assessment to the operator.

26.435 **Automatic deployment of an emergency flotation system**

(a) Operators of small helicopters that are required, in accordance with point CAT.IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be designed for landing on water or certified for ditching, shall ensure that if an emergency flotation system is installed and is stowed during flight, then it shall automatically deploy as a result of entry into water.

(b) Operators of small category A helicopters and large helicopters that are required, in accordance with point CAT.IDE.H.320(a) of Annex IV to Regulation (EU) No 965/2012, to be designed for landing on water or certified for ditching, shall ensure that if an emergency flotation system is installed and is stowed during flight, then it shall automatically deploy as a result of entry into water and shall not rely on any pilot action during flight.';

(6) Appendix 1 is replaced by the following:

'*Appendix 1*

List of aeroplane models not subject to certain provisions of Annex I (Part-26)

Table A.1

TC Holder	Type	Models	Manufacturer serial number	Provisions of Annex I (Part-26) that do NOT apply
The Boeing Company	707	All		26.301 to 26.334
The Boeing Company	720	All		26.301 to 26.334
The Boeing Company	DC-10	DC-10-10 DC-10-30 DC-10-30F	All	26.301 to 26.334
The Boeing Company	DC-8	All		26.301 to 26.334
The Boeing Company	DC-9	DC-9-11, DC-9-12, DC-9-13, DC-9-14, DC-9-15, DC-9-15F, DC-9-21, DC-9-31, DC-9-32, DC-9-32 (VC-9C), DC-9-32F, DC-9-32F (C-9A, C-9B), DC-9-33F, DC-9-34, DC-9-34F, DC-9-41, DC-9-51	All	26.301 to 26.334
The Boeing Company	MD-90	MD-90-30	All	26.301 to 26.334
FOKKER SERVICES B.V.	F27	Mark 100, 200, 300, 400, 500, 600, 700	All	26.301 to 26.334
FOKKER SERVICES B.V.	F28	Mark 1000, 1000C, 2000, 3000, 3000C, 3000R, 3000RC, 4000	All	26.301 to 26.334
GULFSTREAM AEROSPACE CORP.	G-159	G-159 (Gulfstream I)	All	26.301 to 26.334

GULFSTREAM AEROSPACE CORP.	G-II_III_IV_-V	G-1159A (GIII) G-1159B (GIIB) G-1159 (GII)	All	26.301 to 26.334
KELOWNA FLIGHTCRAFT LTD.	CONVAIR 340/440	440	All	26.301 to 26.334
LEARJET INC.	Learjet 24/25/31/36/35/55/60	24, 24A, 24B, 24B-A, 24D,24D-A, 24F, 24F-A, 25, 25B, 25C, 25D, 25F	All	26.301 to 26.334
LOCKHEED MARTIN CORPORATION	1329	All		26.301 to 26.334
LOCKHEED MARTIN CORPORATION	188	All		26.301 to 26.334
LOCKHEED MARTIN CORPORATION	382	382, 382B, 382E, 382F, 382G	All	26.301 to 26.334
LOCKHEED MARTIN CORPORATION	L-1011	All		26.301 to 26.334
PT. DIRGANTARA INDONESIA	CN-235	All		26.301 to 26.334
SABRELINER CORPORATION	NA-265	NA-265-65	All	26.301 to 26.334
VIKING AIR LIMITED	SD3	SD3-30 Sherpa SD3 Sherpa	All	26.301 to 26.334
VIKING AIR LIMITED	DHC-7	All		26.301 to 26.334
VIKING AIR LIMITED	CL-215	CL-215-6B11	All	26.301 to 26.334
TUPOLEV PUBLIC STOCK COMPANY	TU-204	204-120CE	All	26.301 to 26.334
AIRBUS	A320 series	A320-251N, A320-271N	10033, 10242, 10281 and 10360	26.60
AIRBUS	A321 series	A321-271NX	10257, 10371 and 10391	26.60
AIRBUS	A330 series	A330-243, A330-941	1844, 1861, 1956, 1978, 1982, 1984, 1987, 1989, 1998, 2007, 2008 and 2011	26.60

ATR-GIE Avions de Transport Régional	ATR 72 series	ATR72-212A	1565, 1598, 1620, 1629, 1632, 1637, 1640, 1642, 1649, 1657, 1660, 1661	26.60
The Boeing Company	737 series	737-8 and 737-9	43299, 43304, 43305, 43310, 43321, 43322, 43332, 43334, 43344, 43348, 43391, 43579, 43797, 43798, 43799, 43917, 43918, 43919, 43921, 43925, 43927, 43928, 43957, 43973, 43974, 43975, 43976, 44867, 44868, 44873, 60009, 60010, 60040, 60042, 60056, 60057, 60058, 60059, 60060, 60061, 60063, 60064, 60065, 60066, 60068, 60194, 60195, 60389, 60434, 60444, 60455, 61857, 61859, 61862, 61864, 62451, 62452, 62453, 62454, 62533, 63358, 63359, 63360, 64610, 64611, 64612, 62613, 64614, 65899, 66147, 66148, 66150	26.60
GULFSTREAM AEROSPACE LP.	Gulfstream G100 series	1125 Astra 1125 Astra SP G100/Astra SPX	All	26.157
GULFSTREAM AEROSPACE LP.	Gulfstream G100 series	Gulfstream G150	All	26.157
GULFSTREAM AEROSPACE LP.	GALAXY G200 series	Gulfstream 200/Galaxy	All	26.157

TEXTRON AVIATION INC.	650 series	650	All	26.157
TEXTRON AVIATION INC.	Cessna 500/ 550/S550/ 560/560XL series	500 550 560 560XL S550	All	26.157
TEXTRON AVIATION INC.	Hawker Series	BAe.125 Series Hawker 750 Hawker 800XP	All	26.157
TEXTRON AVIATION INC.	CESSNA 750 (Citation X) series	750	All	26.157’

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1255

of 19 July 2022

designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ([1]), and in particular Article 37(5) thereof,

Whereas:

(1) Regulation (EU) 2019/6 sets a broad range of concrete measures to fight antimicrobial resistance and to promote a more prudent and responsible use of antimicrobial medicinal products in animals, including very strict rules on their veterinary prescription for prophylactic and metaphylactic use. That Regulation also recalls that antimicrobial medicinal products should not be administered routinely nor used to compensate for poor hygiene, inadequate animal husbandry, lack of care or to compensate for poor farm management.

(2) Certain antimicrobial medicinal products or groups of antimicrobial medicinal products should be reserved for treatment of certain infections in humans, with a view to better preserve their efficacy for human medicine and to supporting the fight against antimicrobial resistance, which is a major threat to global health.

(3) The antimicrobial medicinal products or groups of antimicrobial medicinal products to be reserved for treatment of certain infections in humans are to be designated on the basis of the criteria set for this purpose in Commission Delegated Regulation (EU) 2021/1760 ([2]).

(4) The European Medicines Agency ('the Agency') evaluated ([3]) antimicrobials and groups of antimicrobials used in medicinal products authorised in Member States and in third countries. It identified which antimicrobials and groups of antimicrobials fulfilled the criteria set in Delegated Regulation (EU) 2021/1760, taking into consideration the latest available scientific evidence. The Agency's advice is based, in accordance with Article 37(6) of Regulation (EU) 2019/6, on the joint opinion of experts in human medicine and of experts in veterinary medicine from national competent authorities, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the Agency itself, as well as of external experts on human infectious diseases from learned societies and academia.

(5) Pursuant to the Agency's advice, several antibiotics, several antivirals and one antiprotozoal fulfilled the criteria established under Delegated Regulation (EU) 2021/1760 and should therefore be reserved for the treatment of certain infections in humans. Pursuant to the Agency's advice, none of the antifungals evaluated met those criteria.

([1]) OJ L 4, 7.1.2019, p. 43.

([2]) Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans (OJ L 353, 6.10.2021, p. 1).

([3]) Advice on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans – in relation to implementing measures under Article 37(5) of Regulation (EU) 2019/6 on veterinary medicinal products (EMA/CVMP/678496/2021, 16 February 2022).

(6) The antimicrobials and group of antimicrobials listed in this Regulation should not be used in veterinary medicinal products. Thus, marketing authorisation applications for veterinary medicinal products that contain any of the antimicrobials or groups of antimicrobials listed in this Regulation should be refused. In addition, existing marketing authorisations of veterinary medicinal products containing such antimicrobials or groups of antimicrobials should cease to be valid.

(7) Veterinary medicinal products are sometimes administered to animals through medicated feed. The use of veterinary medicinal products that contain antimicrobials or groups of antimicrobials listed in this Regulation in medicated feed should not be possible.

(8) Moreover, medicinal products that contain any of the antimicrobials or groups of antimicrobials listed in this Regulation should not be used in animals, even under the conditions set in Articles 112, 113 and 114 of Regulation (EU) 2019/6.

(9) With a view to giving veterinarians, owners of animals and economic operators concerned the necessary time to adjust to the consequences referred to above, this Regulation should apply six months after its entry into force.

(10) The list of antimicrobials or groups of antimicrobials to be reserved for treatment of certain infections in humans, as provided for in this Regulation should be kept under continual review in the light of new scientific evidence or emerging information, including the emergence of new diseases, changes in the epidemiology of existing diseases, changes in antimicrobial drug resistance or changes in availability or patterns of antimicrobial use.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

Article 1

Antimicrobials or groups of antimicrobials designated as reserved for treatment of certain infections in humans

1. The antimicrobials and groups of antimicrobials listed in the Annex shall not be used in veterinary medicinal products or medicated feed.

2. The use in animals of medicinal products for human use that contain any of the antimicrobials or groups of antimicrobials listed in the Annex is prohibited.

Article 2

Entry into force and application

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

It shall apply from 9 February 2023.

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans

(1) Antibiotics
- (a) Carboxypenicillins
- (b) Ureidopenicillins
- (c) Ceftobiprole
- (d) Ceftaroline
- (e) Combinations of cephalosporins with beta-lactamase inhibitors
- (f) Siderophore cephalosporins
- (g) Carbapenems
- (h) Penems
- (i) Monobactams
- (j) Phosphonic acid derivates
- (k) Glycopeptides
- (l) Lipopeptides
- (m) Oxazolidinones
- (n) Fidaxomicin
- (o) Plazomicin
- (p) Glycylcyclines
- (q) Eravacycline
- (r) Omadacycline

(2) Antivirals
- (a) Amantadine
- (b) Baloxavir marboxil
- (c) Celgosivir
- (d) Favipiravir
- (e) Galidesivir
- (f) Lactimidomycin
- (g) Laninamivir
- (h) Methisazone/metisazone
- (i) Molnupiravir
- (j) Nitazoxanide
- (k) Oseltamivir
- (l) Peramivir
- (m) Ribavirin
- (n) Rimantadine
- (o) Tizoxanide
- (p) Triazavirin
- (q) Umifenovir
- (r) Zanamivir

(3) Antiprotozoals
- (a) Nitazoxanide

DECISIONS

COUNCIL DECISION (EU) 2022/1256

of 15 July 2022

on the position to be taken on behalf of the European Union at the 226th session of the Council of the International Civil Aviation Organization as regards the proposed adoption of Amendment 48 to Annex 6, Part I, to the Convention on International Civil Aviation

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 100(2) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Convention on International Civil Aviation ('the Chicago Convention'), which regulates international air transport, entered into force on 4 April 1947. It established the International Civil Aviation Organization (ICAO).

(2) The Member States of the Union are contracting States to the Chicago Convention ('the contracting States') and members of the ICAO, while the Union has observer status in certain ICAO bodies. There are currently seven Member States represented in the ICAO Council.

(3) Pursuant to Article 54 of the Chicago Convention, the ICAO Council is to adopt international standards and recommended practices and designate them as Annexes to the Chicago Convention (the 'Annexes').

(4) Pursuant to Article 90 of the Chicago Convention, any Annex or any amendment of such an Annex is to become effective within three months after its submission to the contracting States, or at the end of such longer period of time as the ICAO Council may prescribe, unless in the meantime a majority of the contracting States register their disapproval with the ICAO Council.

(5) The ICAO Council, at its 226th session, is to adopt Amendment 48 to Annex 6, Part I, to the Chicago Convention ('Amendment 48').

(6) The main purpose of Amendment 48 is to postpone the date of applicability of Annex 6, Part I, standard 6.18.1 to 1 January 2025.

(7) It is appropriate to establish the position to be taken on the Union's behalf at the 226th session of the ICAO Council with regard to Amendment 48. That position should be to support Amendment 48 and should be expressed by the Member States of the Union that are members of the ICAO Council, acting jointly on behalf of the Union.

(8) The position of the Union after the adoption by the ICAO Council of Amendment 48, to be announced by the ICAO Secretary-General by means of an ICAO State letter procedure, should be not to register disapproval, provided that Amendment 48 is adopted without any substantial changes,

HAS ADOPTED THIS DECISION:

Article 1

1. The position to be taken on the Union's behalf at the 226th session of the ICAO Council, or at any subsequent session thereof, shall be to support the proposed Amendment 48 to Annex 6, Part I, to the Convention on International Civil Aviation ('Amendment 48') in its entirety.

2. The position to be taken on the Union's behalf, provided the ICAO Council adopts Amendment 48 without any substantial changes, shall be not to register disapproval of the adopted Amendment 48 in reply to the relevant ICAO State letter.

Article 2

1. The position referred to in Article 1(1) shall be expressed by the Member States of the Union that are members of the ICAO Council, acting jointly on behalf of the Union.

2. The position referred to in Article 1(2) shall be expressed by all Member States, acting jointly on behalf of the Union.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 15 July 2022.

For the Council
The President
M. BEK

COUNCIL DECISION (EU) 2022/1257

of 18 July 2022

appointing five members and seven alternate members, proposed by the Kingdom of Denmark, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ([1]),

Having regard to the proposals of the Danish Government,

Whereas:

(1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.

(2) On 10 December 2019, the Council adopted Decision (EU) 2019/2157 ([2]), appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025. On 17 February 2020, the Council adopted Decision (EU) 2020/234 ([3]), appointing an alternate member, proposed by the Kingdom of Denmark, of the Committee of the Regions.

(3) Four members' seats on the Committee of the Regions have become vacant following the resignations of Mr Jess LAURSEN, Mr Arne LÆGAARD and Mr Per NØRHAVE, and the end of the national mandate on the basis of which Mr Per Bødker ANDERSEN was proposed for appointment.

(4) Six alternate members' seats on the Committee of the Regions have become vacant following the resignation of Mr Søren WINDELL, and the end of the national mandates on the basis of which Mr Steen Bording ANDERSEN, Ms Vibeke Syppli ENRUM, Mr Erik HØGH-SØRENSEN, Mr Anders Rosenstand LAUGESEN and Mr Evan LYNNERUP OLESEN were proposed for appointment.

(5) A member's seat will become vacant following the appointment of Mr Jens Christian GJESING as an alternate member of the Committee of the Regions.

(6) An alternate member's seat will become vacant following the appointment of Ms Kirsten Maria Meyer JENSEN as a member of the Committee of the Regions.

(7) The Danish Government has proposed the following representatives of regional or local bodies who hold a regional or local authority electoral mandate as members of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025: Mr Bent GRAVERSEN, *Regionsrådsmedlem, Regionsrådet, Region Midtjylland* (Regional Councillor, The Central Denmark Region), Ms Kirsten Maria Meyer JENSEN, *Borgmester, Hillerød Kommune* (Mayor, Hillerød Municipality), Mr Torsten NIELSEN, *2. Viceborgmester, Viborg Kommune* (Second Deputy Mayor, Viborg Municipality), Ms Hanne ROED, *Regionsrådsmedlem, Regionsrådet, Region Midtjylland* (Regional Councillor, The Central Denmark Region), and Mr Peter Sønderby Westphal SØRENSEN, *Borgmester, Horsens Kommune* (Mayor, Horsens Municipality).

([1]) OJ L 139, 27.5.2019, p. 13.

([2]) Council Decision (EU) 2019/2157 of 10 December 2019 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 327, 17.12.2019, p. 78).

([3]) Council Decision (EU) 2020/234 of 17 February 2020 appointing an alternate member, proposed by the Kingdom of Denmark, of the Committee of the Regions (OJ L 47 I, 20.2.2020, p. 6).

(8) The Danish Government has proposed the following representatives of regional or local bodies who hold a regional or local authority electoral mandate as alternate members of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025: Mr Jens Christian GJESING, *Kommunalbestyrelsesmedlem, Haderslev Kommune* (City Council member, Haderslev Municipality), Mr Flemming KNUDSEN, *Regionsrådsmedlem, Regionsrådet, Region Midtjylland* (Regional Councillor, The Central Denmark Region), Mr Tage LEEGAARD, *Regionsrådsmedlem Regionsrådet, Region Nordjylland* (Regional Councillor, The North Denmark Region), Ms Anne MADSEN, *Kommunalbestyrelsesmedlem, Sorø Kommune* (City Council member, Sorø Municipality), Mr Henrik Lena MADSEN, *Byrådsmedlem, Kerteminde Kommune* (City Council member, Kerteminde Municipality), Mr Thomas ROHDEN, *Regionsrådsmedlem, Regionsrådet, Region Hovedstaden* (Regional Councillor, Regional Council, the Capital Region), Mr Mads SØRENSEN, *Borgmester, Varde Kommune* (Mayor, Varde Municipality),

HAS ADOPTED THIS DECISION:

Article 1

The following representatives of regional or local bodies who hold an electoral mandate are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025:

(a) as members:

— Mr Bent GRAVERSEN, *Regionsrådsmedlem, Regionsrådet, Region Midtjylland* (Regional Councillor, The Central Denmark Region),

— Ms Kirsten Maria Meyer JENSEN, *Borgmester, Hillerød Kommune* (Mayor, Hillerød Municipality),

— Mr Torsten NIELSEN, *2. Viceborgmester, Viborg Kommune* (Second Deputy Mayor, Viborg Municipality),

— Ms Hanne ROED, *Regionsrådsmedlem, Regionsrådet, Region Midtjylland* (Regional Councillor, The Central Denmark Region),

— Mr Peter Sønderby Westphal SØRENSEN, *Borgmester, Horsens Kommune* (Mayor, Horsens Municipality),

and

(b) as alternate members:

— Mr Jens Christian GJESING, *Kommunalbestyrelsesmedlem, Haderslev Kommune* (City Council member, Haderslev Municipality),

— Mr Flemming KNUDSEN, *Regionsrådsmedlem, Regionsrådet, Region Midtjylland* (Regional Councillor, The Central Denmark Region),

— Mr Tage LEEGAARD, *Regionsrådsmedlem Regionsrådet, Region Nordjylland* (Regional Councillor, The North Denmark Region),

— Ms Anne MADSEN, *Kommunalbestyrelsesmedlem, Sorø Kommune* (City Council member, Sorø Municipality),

— Mr Henrik Lena MADSEN, *Byrådsmedlem, Kerteminde Kommune* (City Council member, Kerteminde Municipality),

— Mr Thomas ROHDEN, *Regionsrådsmedlem, Regionsrådet, Region Hovedstaden* (Regional Councillor, Regional Council, the Capital Region),

— Mr Mads SØRENSEN, *Borgmester, Varde Kommune* (Mayor, Varde Municipality).

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 July 2022.

For the Council
The President
Z. NEKULA

COUNCIL DECISION (EU) 2022/1258

of 18 July 2022

appointing a member and an alternate member, proposed by the Federal Republic of Germany, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ([1]),

Having regard to the proposals of the German Government,

Whereas:

(1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.

(2) On 10 December 2019, the Council adopted Decision (EU) 2019/2157 ([2]), appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.

(3) A member's seat on the Committee of the Regions will become vacant as from 5 September 2022, following the resignation of Mr Bernd LANGE taking effect on 4 September 2022.

(4) The German Government has proposed Mr Thomas HABERMANN, representative of a local body who holds a local authority electoral mandate, *Landrat des Landkreises Rhön-Grabfeld* (District Commissioner of Rhön-Grabfeld), as a member of the Committee of the Regions for the period from 5 September 2022 until the end of the current term of office on 25 January 2025.

(5) An alternate member's seat will become vacant following the appointment of Mr Thomas HABERMANN as a member of the Committee of the Regions as from 5 September 2022.

(6) The German Government has proposed Mr Christoph SCHNAUDIGEL, representative of a local body who holds a local authority electoral mandate, *Landrat des Landkreises Karlsruhe* (District Commissioner of Karlsruhe), as an alternate member of the Committee of the Regions for the period from 5 September 2022 until the end of the current term of office on 25 January 2025,

HAS ADOPTED THIS DECISION:

Article 1

The following representatives of local bodies who hold an electoral mandate are hereby appointed to the Committee of the Regions from 5 September 2022 until 25 January 2025:

(a) as a member:

— Mr Thomas HABERMANN, *Landrat des Landkreises Rhön-Grabfeld* (District Commissioner of Rhön-Grabfeld);

([1]) OJ L 139, 27.5.2019, p. 13.

([2]) Council Decision (EU) 2019/2157 of 10 December 2019 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 327, 17.12.2019, p. 78).

and

(b) as an alternate member:

— Mr Christoph SCHNAUDIGEL, *Landrat des Landkreises Karlsruhe* (District Commissioner of Karlsruhe).

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 July 2022.

For the Council
The President
Z. NEKULA

COUNCIL DECISION (EU) 2022/1259

of 18 July 2022

appointing a member, proposed by the Grand Duchy of Luxembourg, of the European Economic and Social Committee

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to Council Decision (EU) 2019/853 of 21 May 2019 determining the composition of the European Economic and Social Committee ([1]),

Having regard to the proposal of the Luxembourg Government,

After consulting the European Commission,

Whereas:

(1) Pursuant to Article 300(2) of the Treaty, the Economic and Social Committee is to consist of representatives of organisations of employers, of the employed, and of other parties representative of civil society, notably in socioeconomic, civic, professional and cultural areas.

(2) On 2 October 2020, the Council adopted Decision (EU) 2020/1392 ([2]) appointing the members of the European Economic and Social Committee for the period from 21 September 2020 to 20 September 2025.

(3) A member's seat on the European Economic and Social Committee has become vacant following the resignation of Ms Claudine OTTO.

(4) The Luxembourg Government has proposed Ms Christel CHATELAIN, *Directrice des Affaires Économiques – Chambre de Commerce du Grand-Duché de Luxembourg*, as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2025,

HAS ADOPTED THIS DECISION:

Article 1

Ms Christel CHATELAIN, *Directrice des Affaires Économiques – Chambre de Commerce du Grand-Duché de Luxembourg*, is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2025.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 July 2022.

For the Council
The President
Z. NEKULA

([1]) OJ L 139, 27.5.2019, p. 15.

([2]) Council Decision (EU) 2020/1392 of 2 October 2020 appointing the members of the European Economic and Social Committee for the period from 21 September 2020 to 20 September 2025, and repealing and replacing the Council Decision appointing the members of the European Economic and Social Committee for the period 21 September 2020 to 20 September 2025 adopted on 18 September 2020 (OJ L 322, 5.10.2020, p. 1).

COUNCIL DECISION (EU) 2022/1260

of 18 July 2022

appointing a member, proposed by the Kingdom of Denmark, of the European Economic and Social Committee

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to Council Decision (EU) 2019/853 of 21 May 2019 determining the composition of the European Economic and Social Committee ([1]),

Having regard to the proposal of the Danish Government,

After consulting the European Commission,

Whereas:

(1) Pursuant to Article 300(2) of the Treaty, the Economic and Social Committee is to consist of representatives of organisations of employers, of the employed, and of other parties representative of civil society, notably in socioeconomic, civic, professional and cultural areas.

(2) On 2 October 2020, the Council adopted Decision (EU) 2020/1392 ([2]), appointing the members of the European Economic and Social Committee for the period from 21 September 2020 to 20 September 2025.

(3) A member's seat on the European Economic and Social Committee has become vacant following the resignation of Mr Nils TRAMPE.

(4) The Danish Government has proposed Ms Christiane MIßLBECK-WINBERG, *Europapolitisk chef, Dansk Arbejdsgiverforening (DA)* (Director, EU and International Affairs, Confederation of Danish Employers (DA)), as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2025,

HAS ADOPTED THIS DECISION:

Article 1

Ms Christiane MIßLBECK-WINBERG, *Europapolitisk chef, Dansk Arbejdsgiverforening (DA)* (Director, EU and International Affairs, Confederation of Danish Employers (DA)), is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2025.

Article 2

This Decision shall enter into force on the date of its adoption.

([1]) OJ L 139, 27.5.2019, p. 15.

([2]) Council Decision (EU) 2020/1392 of 2 October 2020 appointing the members of the European Economic and Social Committee for the period from 21 September 2020 to 20 September 2025, and repealing and replacing the Council Decision appointing the members of the European Economic and Social Committee for the period 21 September 2020 to 20 September 2025 adopted on 18 September 2020 (OJ L 322, 5.10.2020, p. 1).

Done at Brussels, 18 July 2022.

For the Council
The President
Z. NEKULA

COUNCIL DECISION (EU) 2022/1261

of 18 July 2022

appointing an alternate member, proposed by the Kingdom of Spain, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to Council Decision (EU) 2019/852 of 21 May 2019 determining the composition of the Committee of the Regions ([1]),

Having regard to the proposal of the Spanish Government,

Whereas:

(1) Pursuant to Article 300(3) of the Treaty, the Committee of the Regions is to consist of representatives of regional and local bodies who either hold a regional or local authority electoral mandate or are politically accountable to an elected assembly.

(2) On 10 December 2019, the Council adopted Decision (EU) 2019/2157 ([2]), appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025.

(3) An alternate member's seat on the Committee of the Regions has become vacant following the end of the national mandate on the basis of which Mr Carlos AGUILAR VÁZQUEZ was proposed for appointment.

(4) The Spanish Government has proposed Mr Juan GARCÍA-GALLARDO FRINGS, representative of a regional body who holds a regional authority electoral mandate, *Vicepresidente de la Junta de Castilla y León* (Vice-President of the Government of the Autonomous Community of Castilla y León), as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025,

HAS ADOPTED THIS DECISION:

Article 1

Mr Juan GARCÍA-GALLARDO FRINGS, representative of a regional body who holds an electoral mandate, *Vicepresidente de la Junta de Castilla y León* (Vice-President of the Government of the Autonomous Community of Castilla y León), is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2025.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 July 2022.

For the Council
The President
Z. NEKULA

([1]) OJ L 139, 27.5.2019, p. 13.
([2]) Council Decision (EU) 2019/2157 of 10 December 2019 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2020 to 25 January 2025 (OJ L 327, 17.12.2019, p. 78).

COUNCIL IMPLEMENTING DECISION (EU) 2022/1262

of 18 July 2022

amending Implementing Decision (EU) 2020/1355 granting temporary support under Regulation (EU) 2020/672 to Romania to mitigate unemployment risks in the emergency following the COVID-19 outbreak

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2020/672 of 19 May 2020 on the establishment of a European instrument for temporary support to mitigate unemployment risks in an emergency (SURE) following the COVID-19 outbreak ([1]), and in particular Article 6(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Further to a request from Romania on 7 August 2020, the Council, by means of Implementing Decision (EU) 2020/1355 ([2]), granted financial assistance to Romania in the form of a loan amounting to a maximum of EUR 4 099 244 587 with a maximum average maturity of 15 years, with a view to complementing Romania's national efforts to address the impact of the COVID-19 outbreak and respond to the socioeconomic consequences of that outbreak for workers and the self-employed.

(2) The loan was to be used by Romania to finance a short-time work scheme, similar measures and health-related measures, as referred to in Article 3 of Implementing Decision (EU) 2020/1355.

(3) The COVID-19 outbreak has immobilised a substantial part of the labour force in Romania. This has led to repeated sudden and severe increases in public expenditure in Romania in respect of new measures, namely those referred to in recitals 11, 12 and 16 to 34 of this Decision, and measures referred to in Article 3, points (a), (c), (d), (e), (f), (g), (h) and (i), of Implementing Decision (EU) 2020/1355.

(4) The COVID-19 outbreak and the extraordinary measures implemented by Romania in 2020, 2021 and 2022 to contain that outbreak and its socioeconomic and health-related impact had, and are still having, a dramatic impact on public finances. In 2020, Romania had a general government deficit and debt of 9,3 % and 47,2 % of gross domestic product (GDP) respectively, which changed to 7,1 % and 48,8 % respectively at the end of 2021. According to the Commission's 2022 spring forecast, Romania is expected to have a general government deficit and debt of 7,5 % and 50,9 % of GDP respectively by the end of 2022. Romania's GDP is projected to increase by 2,6 % in 2022.

(5) On 26 May 2022, Romania requested the Union to extend the list of measures for which financial assistance had already been granted by means of Implementing Decision (EU) 2020/1355 in order to further complement its national efforts undertaken in 2020 to address the impact of the COVID-19 outbreak and respond to the socioeconomic consequences of the outbreak for workers and the self-employed ('the request'). In particular, Romania introduced and further extended a series of short-time work schemes and similar measures set out in recitals 6 to 12.

([1]) OJ L 159, 20.5.2020, p. 1.

([2]) Council Implementing Decision (EU) 2020/1355 of 25 September 2020 granting temporary support under Regulation (EU) 2020/672 to Romania to mitigate unemployment risks in the emergency following the COVID-19 outbreak, (OJ L 314, 29.9.2020, p. 55).

(6) 'Government Emergency Ordinance 30/2020' ([3]), as referred to in Article 3, point (a), of Implementing Decision (EU) 2020/1355, provides for a benefit to employees of employers that reduce or temporarily interrupt their activity because of the effects of the COVID-19 outbreak. The benefit is capped at 75 % of those employees' basic salary (but no more than 75 % of the average gross salary in the economy) for the duration of the state of emergency. The measure was extended by means of 'Government Emergency Ordinance 111/2021' ([4]) until December 2021 and by means of 'Government Emergency Ordinance 2/2022' ([5]) until March 2022.

(7) 'Government Emergency Ordinance 132/2020' ([6]), as referred to in Article 3, point (c), of Implementing Decision (EU) 2020/1355, introduced a short-time work scheme, under which, in the event of a temporary reduction of activity caused by the state of emergency or alert, the employer is able to reduce the working hours of employees by up to 50 %. During the period of working-time reduction, affected employees benefit from an indemnity of 75 % of the difference between the gross salary for normal working time and their actual salary. The measure was amended by means of 'Law 58/2021', which extended it until June 2022, three months after the end of the state of alert.

(8) 'Government Emergency Ordinance 30/2020' ([7]), Article XV, and 'Government Emergency Ordinance 132/2020' ([8]), Article 3, as referred to in Article 3, points (d) and (e), of Implementing Decision (EU) 2020/1355, introduced two measures for the self-employed and the liberal professions. For those who stopped work entirely because of the effects of the COVID-19 outbreak, the State provides a benefit of 75 % of the average gross salary in Romania for the duration of the state of emergency. For those who reduce their working hours, the State provides a benefit of up to 41,5 % of the average gross salary until June 2022, three months after the end of the state of alert. The first measure, as referred to in Article 3, point (d), of Implementing Decision (EU) 2020/1355, has been extended by 'Government Emergency Ordinance 111/2021' ([9]) and 'Government Emergency Ordinance 2/2022'. The second measure, as referred to in Article 3, point (e), of Implementing Decision (EU) 2020/1355, has been extended by 'Law 58/2021' ([10]).

(9) 'Government Emergency Ordinance 132/2020' ([11]), approved by means of 'Law 282/2020' ([12]), and its subsequent amendments 'Government Emergency Ordinance 182/2020' ([13]), 'Government Emergency Ordinance 211/2020 ' ([14]), which was approved by means of 'Law 58/2021' ([15]), 'Government Emergency Ordinance 220/2020' ([16]), 'Government Emergency Ordinance 226/2020' ([17]), 'Government Emergency Ordinance 44/2021' ([18]), 'Government Emergency Ordinance 111/2021' ([19]) and 'Government Emergency Ordinance 2/2022' ([20]), as referred to in Article 3, point (f), of Implementing Decision (EU) 2020/1355, introduced a measure providing a support allowance of 35 % of the due remuneration per working day, for a maximum period of three months, for daily labourers who stop working as a result of the suspension of business activities because of the effects of the COVID-19 outbreak. The measure was extended until June 2022, three months after the end of the state of alert.

([3]) Published in the Official Monitor of Romania no. 231 of 21 March 2020.
([4]) Published in the Official Monitor of Romania no. 945 of 4 October 2021.
([5]) Published in the Official Monitor of Romania no. 61 of 20 January 2022.
([6]) Published in the Official Monitor of Romania no. 720 of 10 August 2020.
([7]) Published in the Official Monitor of Romania no. 231 of 21 March 2020.
([8]) Published in the Official Monitor of Romania no. 720 of 10 August 2020.
([9]) Published in the Official Monitor of Romania no. 945 of 4 October 2021.
([10]) Published in the Official Monitor of Romania no. 345 of 5 April 2021.
([11]) Published in the Official Monitor of Romania no. 720 of 10 August 2020.
([12]) Published in the Official Monitor of Romania no. 1201 of 9 December 2020.
([13]) Published in the Official Monitor of Romania no. 993 of 27 October 2020.
([14]) Published in the Official Monitor of Romania no. 1189 of 7 December 2020.
([15]) Published in the Official Monitor of Romania no. 345 of 5 April 2021.
([16]) Published in the Official Monitor of Romania no. 1326 of 31 December 2020.
([17]) Published in the Official Monitor of Romania no. 1332 of 31 December 2020.
([18]) Published in the Official Monitor of Romania no. 575 of 7 June 2021.
([19]) Published in the Official Monitor of Romania no. 945 of 4 October 2021.
([20]) Published in the Official Monitor of Romania no. 61 of 20 January 2022.

(10) 'Law 19/2020' ([21]), Article 3, as extended by 'Government Emergency Ordinance 147/2020' ([22]), Article 4(3), and 'Government Emergency Ordinance 110/2021' ([23]), Article 7, provided a childcare bonus for employees of the national system of defence, penitentiaries, public-health units and other categories of the public sector established through ministerial orders. The benefit is conditional on the other parent not benefitting from alternative rights that grant days off to parents for the supervision of children in the event of the temporary closure of educational units. That measure can be considered to be a measure similar to short-time work schemes, as referred to in Regulation (EU) 2020/672, as it provides income support to employees, which will help to cover the costs of childcare during school closures and therefore help parents to continue working, thereby preventing putting the employment relationship at risk. The measure has been extended over time, including the school years in 2021 and in 2022, and has also been broadened to include private-sector employees.

(11) 'Law 136/2020' ([24]) and its subsequent amendments, as well as 'Government Emergency Ordinance 70/2020' ([25]), Article 13, as referred to in the request, granted a sick-leave benefit to quarantined persons and persons diagnosed with COVID-19 infection.

(12) 'Government Emergency Ordinance 132/2020' ([26]), Article 6, as referred to in the request, included a measure for one-time financial support of RON 2 500 to employers for each employee working remotely for the purchase of packages of technological goods and services necessary for teleworking activities. The measure applies for employers whose employees have teleworked during the state of emergency and the state of alert for at least 15 working days in 2020. That measure can be considered to be a measure similar to short-time work schemes, as referred to in Regulation (EU) 2020/672, because of its intended purpose and economic effect. By facilitating teleworking in the context of the COVID-19 pandemic, it helps preserve the employment relationship. It also provides income support to employees in the form of a fringe benefit, helping to cover the costs of home-office expenditure to allow the performance of work during lockdown and subsequent restrictions.

(13) Romania also introduced and further extended a series of health-related measures to address the COVID-19 outbreak. In particular, this concerns the measures referred to in recitals 14 to 34.

(14) 'Government Emergency Ordinance 11/2020' ([27]), as extended by 'Government Emergency Ordinance 131/2020 ' ([28]), Article 2, and 'Law 136/2020' ([29]), Article 6, as referred to in Article 3, point (g), of Implementing Decision (EU) 2020/1355, provides for a bonus for additional work for the personnel of the specialty structures of the National Public Health Institute and the county public-health directorates and the public-health directorate of Bucharest who act towards coordinating and implementing measures for the prevention and limitation of events related to the COVID-19 global public-health emergency. The measure provides for a benefit equivalent to 75 % of the basic salary for hours worked over the normal working hours and to 100 % of the basic salary for hours worked on weekends, legal holidays and other days not counted as working days. That measure can be considered to be a health-related measure within the meaning of Regulation (EU) 2020/672. The measure was extended in 2020, 2021 and 2022 and will remain in force for as long as the WHO considers that COVID-19 qualifies as a global pandemic.

([21]) Published in the Official Monitor of Romania no. 209 of 14 March 2020.
([22]) Published in the Official Monitor of Romania no. 790 of 28 August 2020.
([23]) Published in the Official Monitor of Romania no. 945 of 4 October 2021.
([24]) Published in the Official Monitor of Romania no. 634 of 18 July 2020; republished in the Official Monitor of Romania no. 884 of 28 September 2020.
([25]) Published in the Official Monitor of Romania no. 394 of 14 May 2020.
([26]) Published in the Official Monitor of Romania no. 720 of 10 August 2020.
([27]) Published in the Official Monitor of Romania no.102 of 11 February 2020.
([28]) Published in the Official Monitor of Romania no. 720 of 10 August 2020.
([29]) Published in the Official Monitor of Romania no. 634 of 18 July 2020; republished in the Official Monitor of Romania no. 884 of 28 September 2020.

(15) 'Law 56/2020' ([30]), Article 7, and its subsequent amendment by means of 'Government Emergency Ordinance 116/2021' ([31]), as referred to in Article 3, point (i), of Implementing Decision (EU) 2020/1355, grants as a temporary measure a bonus for particularly dangerous working conditions of up to 30 % granted for recognition of the merits of medical personnel who participated in the medical response to COVID-19. The measure was in force for the period March 2020 to August 2020. The measure was broadened to include the personnel responsible for the enforcement of sanitary measures under the Ministry of Internal Affairs.

(16) 'Government Emergency Ordinance 131/2020' ([32]), Article 1(1a) and (1b), as referred to in the request, allows the granting of a bonus of between 30 % and 40 % of the basic salary to the personnel of the county public-health directorates and of the public-health directorate of Bucharest. The executive director and the deputy executive directors are to benefit from a bonus of 40 % of the basic salary; the civil servants employed with the control service in public health are to benefit from a bonus of 30 % of the basic salary.

(17) 'Law 136/2020' ([33]), Article 19(3), as referred to in the request, grants a secondment allowance amounting to 50 % and a per diem bonus of 2 % of the basic salary for medical specialists, paramedical and auxiliary personnel in the public system. The allowance is for the personnel seconded, in situations of epidemiological or biological risk for a term of 30 days, to health units with shortages of personnel, and responsible for limiting and preventing the spread of COVID-19.

(18) 'Government Decision 254/2020' ([34]), Sole Article, 'Government Decision 840/2020' ([35]), Sole Article, 'Government Decision 383/2021' ([36]), Sole Article, 'Government Decision 1072/2021' ([37]) and 'Government Decision 496/2022 ' ([38]), as referred to in the request, provided for the temporary financing of salary costs related to the opening of 2 000 new positions to reinforce the health directorates and the public ambulance services (1 000 in each) in order to counteract the spread of COVID-19.

(19) 'Government Decision 1035/2020' ([39]), Sole Article, point 3, as referred to in the request, grants a bonus of between 75 % and 85 % of the basic salary for the specialty medical personnel and auxiliary medical personnel from public-health units or the structures thereof, as applicable, and for the specialty personnel from the paraclinical medical structures directly involved in the transport, equipment, assessment, diagnosis and treatment of COVID-19 patients.

(20) 'Government Decision 1031/2020' ([40]) and 'Government Emergency Ordinance 3/2021' ([41]), as referred to in the request, provided for the payment of medical-sanitary personnel and medical registrars who carry out their activity within COVID-19 vaccination centres organised in locations other than those within health units. The measure also financed current and capital expenditures to make the vaccination centres (organised in locations other than health facilities) operational.

(21) 'Government Emergency Ordinance 3/2021' ([42]) and 'Government Decision 1031/2020' ([43]), as referred to in the request, provided for the payment of medical-sanitary personnel and medical registrars who carry out their activity within COVID-19 vaccination centres organised in health units, as well as the payment of the family doctors for the activities provided for those purposes.

([30]) Published in the Official Monitor of Romania no. 402 of 15 May 2020.
([31]) Published in the Official Monitor of Romania no. 951 of 5 October 2021.
([32]) Published in the Official Monitor of Romania no. 720 of 10 August 2020.
([33]) Published in the Official Monitor of Romania no. 634 of 18 July 2020; republished in the Official Monitor of Romania no. 884 of 28 September 2020.
([34]) Published in the Official Monitor of Romania no. 272 of 1 April 2020.
([35]) Published in the Official Monitor of Romania no. 924 of 9 October 2020.
([36]) Published in the Official Monitor of Romania no. 335 of 1 April 2021.
([37]) Published in the Official Monitor of Romania no. 951 of 5 October 2021.
([38]) Published in the Official Monitor of Romania no. 357 of 11 April 2022.
([39]) Published in the Official Monitor of Romania no. 1179 of 4 December 2020.
([40]) Published in the Official Monitor of Romania no. 1171 of 3 December 2020.
([41]) Published in the Official Monitor of Romania no. 50 of 15 January 2021.
([42]) Published in the Official Monitor of Romania no. 50 of 15 January 2021.
([43]) Published in the Official Monitor of Romania no. 1171 of 3 December 2020.

(22) 'Government Decision 1031/2020' ([44]), as referred to in the request, regulated the purchase of COVID-19 vaccine doses. The framework agreements have been concluded by the Commission on behalf of and for the Member States.

(23) 'Government Decision 201/2020' ([45]), 'Government Decision 1103/2020' ([46]) and 'Minister of Health Order 725/2020' ([47]), as referred to in the request, regulated the expenses for the quarantine of people in designated areas with confirmed diagnosis of COVID-19, people on the list established by the COVID-19 Surveillance Methodology and medical staff diagnosed with COVID-19 who do not require hospitalisation or staff who interacted with patients and choose to stay away from their home. The measure covers general allowances (for items such as food, accommodation, transport and medicines).

(24) 'Government Decision 1092/2020' ([48]), 'Government Decision 380/2021' ([49]), 'Government Decision 1017/2021 ' ([50]) and 'Government Decision 1190/2021' ([51]) provided for the purchase of the medication Remdesivir and of monoclonal antibody medicine for COVID-19 treatment that contains Casirivimab and Imdevimab. The procurement procedures for both medications have been conducted by the Commission on behalf of the Member States within framework contracts ([52]), as referred to in the request.

(25) 'Minister of Health Order 487/2020' ([53]), as referred to in the request, provided for the purchase of medications for the treatment of COVID-19 infected patients. The Ministry of Health concluded a framework contract for the procurement of Tocilizumabum.

(26) 'Government Ordinance 19/2021' ([54]) and 'Law 55/2020' ([55]), as referred to in the request, provided for incentives, in the form of meal vouchers in the amount of RON 100, to fully vaccinated persons.

(27) 'Government Emergency Ordinance 131/2020' ([56]), Article 5, as referred to in the request, provided for a temporary increase of 30 % in the basic salary for the staff of the prefect's institutions involved in preventing and fighting the effects of COVID-19 for the period from August 2020 to February 2021.

(28) 'Government Emergency Ordinance 186/2020' ([57]), as referred to in the request, covered the expenditures of 200 additional resident doctors needed because of the pandemic.

(29) 'Government Emergency Ordinance 11/2020' ([58]), as referred to in the request, provided for the purchase of medical products and personal protective equipment for the fight against the pandemic (e.g., protective footwear, gloves, masks, ventilators and stretchers) in order to establish and consolidate emergency medical stocks.

(30) 'Law 319/2006' ([59]), 'Law 55/2020' ([60]) and 'Minister of Labor and Minister of Health Joint Order 3577/831/2020 ' ([61]), as referred to in the request, regulated the purchase of sanitary protection materials for the employees of the Ministry of Internal Affairs.

(31) 'Government Emergency Ordinance 197/2020' ([62]), as referred to in the request, provided for payments to volunteer medicine students who worked for hospitals or healthcare institutions to provide emergency support.

([44]) Published in the Official Monitor of Romania no. 1171 of 3 December 2020.
([45]) Published in the Official Monitor of Romania no. 224 of 19 March 2020.
([46]) Published in the Official Monitor of Romania no. 1259 of 18 December 2020.
([47]) Published in the Official Monitor of Romania no. 350 of 30 April 2020.
([48]) Published in the Official Monitor of Romania no. 1251 of 17 December 2020.
([49]) Published in the Official Monitor of Romania no. 328 of 31 March 2021.
([50]) Published in the Official Monitor of Romania no. 935 of 30 September 2021.
([51]) Published in the Official Monitor of Romania no. 1081 of 11 November 2021.
([52]) Framework agreement SANTE/2020/C3/048 for Remdivisir and framework agreement SANTE/2020/C3/091 for monoclonal antibody medicine.
([53]) Published in the Official Monitor of Romania no. 242 of 24 March 2020.
([54]) Published in the Official Monitor of Romania no. 834 of 31 August 2021.
([55]) Published in the Official Monitor of Romania no. 396 of 15 May 2020.
([56]) Published in the Official Monitor of Romania no. 720 of 10 August 2020.
([57]) Published in the Official Monitor of Romania no. 1005 of 29 October 2020.
([58]) Published in the Official Monitor of Romania no. 102 of 11 February 2020.
([59]) Published in the Official Monitor of Romania no. 646 of 26 July 2006.
([60]) Published in the Official Monitor of Romania no. 396 of 15 May 2020.
([61]) Published in the Official Monitor of Romania no. 403 of 16 May 2020.
([62]) Published in the Official Monitor of Romania no. 1108 of 19 November 2020.

(32) 'Minister of Health Order 487/2020' ([63]), as referred to in the request, provided for the purchase of two pharmaceutical products (Molnupiravir and Anakinra) which are used for the treatment of COVID-19 patients.

(33) 'Law 95/2006' ([64]), Article 51, 'Government Decision 155/2017' ([65]) and 'Minister of Health Order 377/2017' ([66]) as referred to in the request, regulated the funding of testing for COVID-19 at the level of specialised units. RT-PCR laboratory testing services financed under the National Program for Surveillance and Control of Priority Communicable Diseases are performed on categories of individuals established by the new COVID-19 Acute Respiratory Syndrome Surveillance Methodology or by order of the Minister of Health.

(34) 'Minister of Health Order 58/4/2022' ([67]), as referred to in the request, regulated the funding of COVID-19 testing by family doctors. The testing work carried out by family doctors is financed by transfers from the State budget, through the Ministry of Health's budget to the budget of the Single National Health Insurance Fund.

(35) Romania fulfils the conditions for requesting financial assistance set out in Article 3 of Regulation (EU) 2020/672. Romania has provided the Commission with appropriate evidence that the actual and planned public expenditure has increased by EUR 3 321 482 911 as of 1 February 2020 as a result of the national measures taken to address the socioeconomic effects of the COVID-19 outbreak. This constitutes a sudden and severe increase because it is related to both new measures and the extension of existing measures directly related to short-time work schemes and similar measures that cover a significant proportion of undertakings and of the labour force in Romania. Romania intends to finance EUR 353 704 624 of the increased amount of expenditure through Union funds.

(36) The Commission has consulted Romania and verified the sudden and severe increase in the actual and planned public expenditure directly related to short-time work schemes and similar measures, as well as the recourse to relevant health-related measures related to the COVID-19 outbreak, as referred to in the request, in accordance with Article 6 of Regulation (EU) 2020/672.

(37) The expenditure on health-related measures by Romania, including the additional or extended health-related measures referred to in recitals 14 to 34, amounts to EUR 2 141 579 582. Given the need to ensure the ancillary nature of this category of measures, the amount of the financial assistance in support of health-related measures needs to be reduced as it should represent less than half of the total financial assistance planned to be spent on all eligible measures.

(38) Financial assistance already granted by means of Implementing Decision (EU) 2020/1355 should therefore also cover the new measures referred to in recitals 11, 12 and 16 to 34.

(39) The financial assistance granted by means of Implementing Decision (EU) 2020/1355 should be reduced from EUR 4 099 244 587 to EUR 3 000 000 000. Romania remains committed to fully absorbing the financial assistance granted and should identify further eligible measures in case the existing measures prove insufficient.

(40) Romania and the Commission should take this Decision into account in the loan agreement referred to in Article 8(2) of Regulation (EU) 2020/672.

(41) This Decision should be without prejudice to the outcome of any procedures relating to distortions of the operation of the internal market that may be undertaken, in particular pursuant to Articles 107 and 108 of the Treaty. It does not override the requirement for Member States to notify instances of potential State aid to the Commission under Article 108 of the Treaty.

([63]) Published in the Official Monitor of Romania no. 242 of 24 March 2020.
([64]) Published in the Official Monitor of Romania no. 372 of 28 April 2006; republished in the Official Monitor of Romania no. 652 of 28 August 2015.
([65]) Published in the Official Monitor of Romania no. 222 of 31 March 2017.
([66]) Published in the Official Monitor of Romania no. 223 of 31 March 2017.
([67]) Published in the Official Monitor of Romania no. 33 of 11 January 2022.

(42) Romania should inform the Commission on a regular basis of the implementation of the planned public expenditure, in order to enable the Commission to assess the extent to which Romania has implemented that expenditure,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision (EU) 2020/1355 is amended as follows:

(1) in Article 2, paragraph 1 is replaced by the following:

'1. The Union shall make available to Romania a loan amounting to a maximum of EUR 3 000 000 000. The loan shall have a maximum average maturity of 15 years.';

(2) Article 3 is replaced by the following:

'*Article 3*

Romania may finance the following measures:

(a) the technical unemployment benefit to employees of employers that reduce or temporarily interrupt their activity, as provided for in 'Government Emergency Ordinance 30/2020', Article XI, as extended by 'Government Emergency Ordinance 111/2021', in turn extended by 'Government Emergency Ordinance 2/2022';

(b) the benefit applied for persons whose employment contract was suspended, as provided for in 'Government Emergency Ordinance 92/2020', Article I;

(c) the short-time work scheme, as provided for in 'Government Emergency Ordinance 132/2020', Article 1, as amended and extended by 'Law 58/2021';

(d) the benefit similar to that referred to in point (a) for categories other than employees, including the self-employed and the liberal professions, as provided for in 'Government Emergency Ordinance 30/2020', Article XV, as extended by 'Government Emergency Ordinance 111/2021', in turn extended by 'Government Emergency Ordinance 2/2022';

(e) the benefit provided for other categories than employees, including the self-employed and the liberal professions, as provided for in 'Government Emergency Ordinance 132/2020', Article 3, as amended and extended by 'Law 58/2021';

(f) the support allowance to daily labourers as provided for in 'Government Emergency Ordinance 132/2020', Article 4 (approved by means of 'Law 282/2020'), and its subsequent amendments 'Government Emergency Ordinance 182/2020', 'Government Emergency Ordinance 211/2020' (approved by means of 'Law 58/2021'), 'Government Emergency Ordinance 220/2020', 'Government Emergency Ordinance 226/2020', 'Government Emergency Ordinance 44/2021', 'Government Emergency Ordinance 111/2021', and 'Government Emergency Ordinance 2/2022';

(g) the bonus in respect of additional work for the personnel of the specialty structures of the National Public Health Institute and the county public-health directorates and the public-health directorate of Bucharest, as provided for in 'Government Emergency Ordinance 11/2020', Article 8(6), as extended by 'Government Emergency Ordinance 131/2020', Article 2 and 'Law 136/2020', Article 6;

(h) the childcare bonus granted to private-sector employees and to employees of the national system of defence, penitentiaries, public-health units and other categories established through ministerial orders, as provided for in 'Government Emergency Ordinance 30/2020', Article I(6); as extended by 'Government Emergency Ordinance 147/2020', Article 4(3) and 'Government Emergency Ordinance 110/2021', Article 7;

(i) the bonus in respect of particularly dangerous conditions granted in recognition of the merits of medical personnel, as provided for in 'Law 56/2020', Article 7, as extended by 'Government Emergency Ordinance 116/2021';

(j) the sick-leave benefit granted to quarantined persons and persons diagnosed with COVID-19 infection, as provided for in 'Law 136/2020', and amended by 'Government Emergency Ordinance 70/2020', Article 13;

(k) the one-time financial support granted to employers in order for employees to carry out teleworking activities, as provided for in 'Government Emergency Ordinance 132/2020', Article 6;

(l) the bonus of 30 % and 40 % of the basic salary granted to the personnel of the county public-health directorates and of the public-health directorate of Bucharest, as provided for in 'Government Emergency Ordinance 131/2020', Article 1(1);

(m) the granting of a secondment allowance amounting to 50 % and a per diem bonus of 2 % of the basic salary for medical specialists, paramedical and auxiliary personnel in the public system, as provided for in 'Government Emergency Ordinance 136/2020', Article 19(3);

(n) the temporary financing of salary costs related to the opening of 2 000 positions to reinforce the health directorates and the public ambulance services (1 000 in each) in order to counteract the spread of COVID-19, as provided for in 'Government Decision 254/2020, Sole Article', 'Government Decision 840/2020', Sole Article, 'Government Decision 383/2021', Sole Article, 'Government Decision 1072/2021' and 'Government Decision 496/2022';

(o) the granting of a bonus of 75 % to 85 % of the basic salary for the specialty medical personnel and auxiliary medical personnel from public-health units or the structures thereof and for the specialty personnel from the paraclinical medical structures directly involved in the transport, equipment, assessment, diagnosis and treatment of COVID-19 patients, as provided for in 'Government Decision 1035/2020', Sole Article, point 3;

(p) the payment of medical-sanitary personnel and medical registrars who carry out their activity within COVID-19 vaccination centres organised in locations other than those within health units, as provided for in 'Government Decision 1031/2020' and 'Government Emergency Ordinance 3/2021';

(q) the payment of medical-sanitary personnel and medical registrars who carry out their activity within COVID-19 vaccination centres organised in health units, as well as the payment of family doctors for the activities provided for those purposes, as provided for in 'Government Emergency Ordinance 3/2021' and 'Government Decision 1031/2020';

(r) the purchase of COVID-19 vaccine doses, as provided for in 'Government Decision 1031/2020';

(s) the expenses for the quarantine of people with a confirmed diagnosis of COVID-19, people on the list established by the COVID-19 Surveillance Methodology and medical staff diagnosed with COVID-19 who do not require hospitalisation or staff who interacted with patients and choose to stay away from home, as provided for in 'Government Decision 201/2020', 'Government Decision 1103/2020' and 'Ministerial Order 725/2020';

(t) the purchase of medication (Remdesivir), as provided for in 'Government Decision 1092/2020', 'Government Decision 380/2021', 'Government Decision 1017/2021' and 'Government Decision 1190/2021';

(u) the purchase of medication (Tocilizumabum), as provided for in 'Minister of Health Order 487/2020';

(v) the purchase of monoclonal antibody medicine for COVID-19 treatment that contains Casirivimab and Imdevimab, as provided for in 'Government Decision 1092/2020', 'Government Decision 380/2021', 'Government Decision 1017/2021' and 'Government Decision 1190/2021';

(w) meal vouchers for persons who are fully vaccinated in the amount of RON 100, as provided for in 'Government Ordinance 19/2021', amending 'Law 55/2020';

(x) the 30 % basic salary increase for the staff of the prefect's institutions involved in preventing and fighting the effects of COVID-19, as provided for in 'Government Emergency Ordinance 131/2020', Article 5;

(y) the expenditures to cover 200 additional resident doctors needed because of the pandemic, as provided for in 'Government Emergency Ordinance 186/2020';

(z) the purchase of medical products and personal protective equipment for the fight against the pandemic (e.g., protective footwear, gloves, masks, ventilators, stretchers), as provided for in 'Government Emergency Ordinance 11/2020';

(aa) the purchase of sanitary protection materials for personnel, as provided for in 'Law 319/2006', 'Law 55/2020', and 'Minister of Labor and Minister of Health Joint Order 3577/831/2020';

(bb) payments to volunteer medicine students who worked for hospitals or healthcare institutions to provide emergency support, as provided for in 'Government Emergency Ordinance 197/2020';

(cc) the purchase of medication for the treatment of COVID-19 infections (ANAKINRA), as provided for in 'Minister of Health Order 487/2020';

(dd) the purchase of medication for the treatment of COVID-19 infections (MOLNUPIRAVIR), as provided for in 'Minister of Health Order 487/2020';

(ee) the financing of COVID-19 testing at the level of specialised units, as provided for in 'Law 95/2006, Article 51', 'Government Decision 155/2017' and 'Minister of Health Order 377/2017';

(ff) the financing of COVID-19 testing by family doctors, as provided for in 'Minister of Health Order 58/4/2022'.';

(3) Article 4 is replaced by the following:

'*Article 4*

1. Romania shall inform the Commission by 30 March 2021, and every six months thereafter, of the implementation of the planned public expenditure until that planned public expenditure has been fully implemented.

2. Where measures referred to in Article 3 are based on planned public expenditure and have been subject to an implementing decision amending Implementing Decision (EU) 2020/1355, Romania shall inform the Commission within six months of the date of adoption of that amending implementing decision, and every six months thereafter, of the implementation of the planned public expenditure until that planned public expenditure has been fully implemented.'.

Article 2

This Decision is addressed to Romania.

This Decision shall take effect on the date of its notification to the addressee.

Article 3

This Decision shall be published in the *Official Journal of the European Union*.

Done at Brussels, 18 July 2022.

For the Council
The President
Z. NEKULA

COMMISSION IMPLEMENTING DECISION (EU) 2022/1263

of 19 July 2022

terminating the anti-subsidy proceeding concerning imports of graphite electrode systems originating in the People's Republic of China

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidised imports from countries not members of the European Union ([1]) ('the basic Regulation'), and in particular Article 14(1) thereof,

Whereas:

1. PROCEDURE

1.1. Initiation of an anti-subsidy proceeding

(1) On 4 October 2021 the Commission received a complaint pursuant to Article 10 of the basic Regulation lodged by Graphite Cova GmbH, Showa Denko Carbon Holding GmbH and Tokai ErftCarbon GmbH ('the complainants').

(2) On 18 November 2021, after holding consultations with the Government of the People's Republic of China on 16 November 2021, the European Commission initiated an anti-subsidy proceeding regarding imports into the Union of graphite electrode systems originating in the People's Republic of China. It published a Notice of Initiation in the *Official Journal of the European Union* (the 'Notice of Initiation') ([2]).

(3) On 6 April 2022, the European Commission imposed definitive duties in a separate anti-dumping proceeding concerning imports of the same product originating in the People's Republic of China ([3]).

1.2. Investigation period and period considered

(4) The investigation period covered the period 1 January 2020 to 31 December 2020. The period considered covered the period 1 January 2017 to 31 December 2020.

1.3. Interested parties

(5) In the Notice of Initiation, interested parties were invited to contact the Commission in order to participate in the investigation. In addition, the Commission specifically informed the complainants, the known Union producers and associations, as well as the Government of the People's Republic of China about the initiation of the investigation and invited them to participate.

(6) Interested parties had an opportunity to comment on the initiation of the investigation and to request a hearing with the Commission and/or the Hearing Officer in trade proceedings.

2. PRODUCT UNDER INVESTIGATION

(7) The product subject to this investigation is graphite electrodes of a kind used for electric furnaces, with an apparent density of 1,5 g/cm^3 or more and an electrical resistance of 7,0 μ.Ω.m or less, whether or not equipped with nipples ('the product under investigation').

([1]) OJ L 176, 30.6.2016, p. 55.

([2]) Notice of initiation of an anti-subsidy proceeding concerning imports of certain graphite electrode systems originating in the People's Republic of China (OJ C 466, 18.11.2021, p. 6).

([3]) Commission Implementing Regulation (EU) 2022/558 of 6 April 2022 imposing a definitive anti-dumping duty and definitively collecting the provisional duty imposed on imports of certain graphite electrode systems originating in the People's Republic of China (OJ L 108, 7.4.2022, p. 20).

3. **WITHDRAWAL OF THE COMPLAINT**

(8) In its letter to the Commission of 9 May 2022 the complainants withdrew their complaint.

(9) In accordance with Article 14(1) of the basic Regulation, the proceeding may be terminated, unless such termination would not be in the Union interest.

(10) The investigation had not brought to light any considerations demonstrating that such termination would not be in the Union interest.

4. **CONCLUSION AND DISCLOSURE**

(11) The Commission therefore considered that the proceeding should be terminated.

(12) Interested parties were informed accordingly and were granted an opportunity to submit comments.

(13) The Commission received no comments which would lead to the conclusion that such termination would not be in the Union interest.

(14) This Decision is in accordance with the opinion of the Committee established by Article 25(1) of the basic Regulation,

HAS ADOPTED THIS DECISION:

Article 1

The anti-subsidy proceeding concerning imports of certain graphite electrode systems originating in the People's Republic of China is hereby terminated.

Article 2

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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