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Legislation

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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) 2022/1490

of 1 March 2022

concerning the authorisation of expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil as feed additives for certain animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

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

(2) Expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. These additives 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, an application was submitted for the re-evaluation of expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil for all animal species.

(4) The applicant requested expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil to be authorised also for use 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 expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil in water for drinking should not be allowed.

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

(5) The applicant requested the additives 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.

(6) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 March 2021 ([3]) that, under the proposed conditions of use of expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil do not have adverse effects on animal health, consumer health or the environment. The Authority concluded that pets (companion animals and ornamental fish) are not normally exposed to expressed lemon essential oil, residual fraction of expressed lemon oil distilled and distilled lime essential oil, therefore, no conclusion can be drawn for those species. Consequently, those additives cannot be authorised for those species. The Authority also concluded that expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil should be considered as skin sensitisers and as irritants to skin and eyes and the respiratory tract and also that expressed lemon oil and its residual fraction contain furocoumarins that may cause phototoxicity. 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 expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil are recognised to flavour food and their function in feed would be essentially the same as that in food, and 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 expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

(9) The fact that expressed lemon essential oil, residual fraction of expressed lemon oil distilled, distilled lemon essential oil (volatile fraction) and distilled lime essential oil are not authorised for use as a flavouring in water for drinking, does not preclude their use in compound feed which is administered via water.

(10) 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.

(11) 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 2021;19(4):6548.

Article 2

Transitional measures

1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 29 March 2023 in accordance with the rules applicable before 29 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 29 September 2023 in accordance with the rules applicable before 29 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 29 September 2024 in accordance with the rules applicable before 29 September 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Entry into force

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

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

Done at Brussels, 1 March 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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b139-eo	-	Expressed lemon essential oil	*Additive composition* Expressed lemon essential oil from fruit peel of *Citrus limon* (L.) Osbeck Liquid form *Characterisation of the active substance* Expressed lemon essential oil obtained by cold expression from fruit peel of *Citrus limon* (L.) Osbeck as defined by the Council of Europe ([1]) d-Limonene: 60–73 % β-Pinene (pin-2(10)-ene): 9–18 % γ-Terpinene: 6–12 % α-Pinene (pin-2(3)-ene): 1,3–3,0 % Sabinene (4(10)-thujene): 0,3–3,0 % Geranial: 0,1–2,0 % Neral: 0,1–1,8 % Perillaldehyde: ≤ 0,023 % Furocoumarins: ≤ 0,3 % Methoxycoumarins: ≤ 0,06 %	Chickens for fattening	-	-	35	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. Mixture of expressed lemon essential oil with other botanical additives is permitted provided that the amounts of perillaldehyde, furocoumarins, and methoxycoumarins in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or animal category. 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	29 September 2032
				Turkeys for fattening Salmonids			40		
				Laying hens			52		
				Pigs for fattening			74		
				Piglets			62		
				Sows			92		
				Calves (milk replacers) Cattle for fattening Dairy cows			90		

			CAS number 84929-31-7 FEMA number 2625 CoE number: 139					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.	
			Analytical method ([2]) For the quantification of phytochemical marker *d-limonene* in the feed additive or in mixture of flavouring compounds: — Gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 855)	Horses			137		
				Sheep/Goats Rabbits			30		
2b139- rf	-	Residual fraction of expressed lemon oil distilled	*Additive composition* Residual fraction of expressed lemon oil distilled from fruit peel of *Citrus limon* (L.) Osbeck Liquid form	Chickens for fattening	-	-	11	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. Mixture of residual fraction of expressed lemon oil distilled with other botanical additives is permitted provided that the amounts of perillaldehyde, furocoumarins, and methoxycoumarins in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or animal category.	29 September 2032
				Laying hens Turkeys for fatening Rabbits Salmonids			12		
			Characterisation of the active substance Residual fraction of expressed lemon oil distilled obtained by the distillation of lemon essential oil expressed from fruit peel of *Citrus limon* (L.) Osbeck The specifications of the active substance are: d-Limonene 5989-27-5 01.045 51–63 53.3 49.-.3–56.8 c-Terpinene 99-85-401.0208–1716.912.8–23-23.3	Ruminants			20		
				Piglets			20		
				Pigs for fattening			24		
				Sows			30		
				Horses			35		

			Geranial 141-27-505.1886–1210.49.5–11-11.2 Neral 106-26-3 0.8724 5–9 7.8 6.2–8.9 b-Pinene (pin-2(10)-ene) 127-91-3 01.003 0.3–5.5 1.24 0.3-32–3.38 b-Bisabolene 495-61-4 01.028 0.3–4 d-Limonene: 51–63 % γ-Terpinene: 8–17 % Geranial: 6–12 % Neral:5–9 % β-Pinene (pin-2(10)-ene): 0,3–5,5 % β-Bisabolene: 0,3–4 % Perillaldehyde: ≤ 0,092 % Furocoumarins: ≤ 0,8 % Methoxycoumarins: ≤ 0,22 % CoE number: 139					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, eye and breathing protection	
			Analytical method (2) For the quantification of phytochemical marker *d-limonene* in the feed additive or in mixture of flavouring compounds: — Gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 855)						

2b139-di	-	Distilled lemon essential oil (volatile fraction)	*Additive composition* Distilled lemon essential oil (volatile fraction) obtained from lemon essential oil expressed, from fruit peel of *Citrus limon* (L.) Osbeck Liquid form	Chickens for fattening	-	-	36	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. Mixture of distilled lemon essential oil (volatile fraction) with other botanical additives is permitted provided that the amounts of perillaldehyde, furocoumarins, and methoxycoumarins in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or animal category. 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, eye and breathing protection.	29 September 2032
				Laying hens			53		
				Rabbits			56		
				Turkeys for fattening			48		
			Characterisation of the active substance Distilled lemon essential oil (volatile fraction) obtained by lemon essential oil expressed, from fruit peel of *Citrus limon* (L.) Osbeck as defined by the Council of Europe [1] The specifications of the active substance are: d-Limonene: 66–78 % β-Pinene (pin-2(10)-ene): 5–20 % γ-Terpinene: 1,5–9,5 % α-Pinene (pin-2(3)-ene): 0,5–3,0 % Sabinene: 0,3–3,0 % Furocoumarins: ≤ 0,1 mg/kg Methoxycoumarins: ≤ 0,1 mg/kg CoE number: 139	Piglets			64		
				Pigs for fattening			76		
				Sows			94		
				Calves (milk replacers) Cattle for fattening Sheep/Goats			95		
				Horses			141		
			Analytical method [2] For the quantification of phytochemical marker *d-limonene* in the feed additive or in mixture of flavouring compounds: — Gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 855)	Dairy cows			91		
				Salmonids Ornamental fish Dogs			60		
				Cats			30		

2b141-eo	-	Distilled lime essential oil	*Additive composition* Distilled lime essential oil obtained by unpeeled fruits of the plant species *Citrus aurantiifolia* (Christm.) Swingle Liquid form *Characterisation of the active substance* Distilled lime essential oil obtained by steam distillation from unpeeled fruits of the plant species *Citrus aurantiifolia* (Christm.) Swingle as defined by the Council of Europe [1] The specifications of the active substance are: d-Limonene: 45–52 % γ-Terpinene: 10–14 % Terpinolene: 5,5–10,5 % αTerpineol: 6–8 % β-Caryophyllene: 0,2–0,8 % Furocoumarins: ≤ 0,0083 % Methoxycoumarins: ≤ 0,03 % CoE number:141 *Analytical method* [2] For the quantification of phytochemical marker *d-limonene* in the feed additive or in mixture of flavouring compounds:	Chickens for fattening	-	-	8,5	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. Mixture of distilled lime essential oil with other botanical additives is permitted provided that the amounts of perillaldehyde, furocoumarins, and methoxycoumarins in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or animal category. 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, eye and breathing protection.	29 September 2032
				Laying hens			12,5		
				Turkeys for fatening			11		
				Piglets			15		
				Pigs for fattening			18		
				Lactating sows			22		
				Cattle for fattening			33,5		
				Calves (milk replacers)			35,5		
				Dairy cows			21,5		
				Sheep/Goats Horses			33,5		
				Rabbits			13,5		
				Salmonids Ornamental fish			30		

			— Gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 855)						

(1) Natural sources of flavourings - Report No. 2 (2007).
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

COMMISSION REGULATION (EU) 2022/1491

of 8 September 2022

amending Regulation (EC) No 1126/2008 as regards International Financial Reporting Standard 17

(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 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards ([1]), and in particular Article 3(1) thereof,

Whereas:

(1) By Commission Regulation (EC) No 1126/2008 ([2]), certain international accounting standards and interpretations that were in existence on 15 October 2008 were adopted.

(2) On 19 November 2021, by Commission Regulation (EU) 2021/2036 ([3]) the Commission adopted the new International Financial Reporting Standard (IFRS) 17 *Insurance Contracts* as issued by the International Accounting Standards Board (IASB) in May 2017 and amended by it in June 2020. That standard is to apply from 1 January 2023 onwards. Earlier application is permitted.

(3) On 9 December 2021, the IASB published a further amendment to IFRS 17. The amendment to the transition requirements in IFRS 17 allows companies to overcome one-time classification differences of comparative information of the previous reporting period upon initial application of IFRS 17 and IFRS 9 *Financial Instruments*.

(4) The optional classification overlay introduced by that amendment enables companies to increase the usefulness of comparative information presented upon the initial application of IFRS 17 and IFRS 9. The scope covers financial assets linked to insurance liabilities, which have not been restated for IFRS 9 so far.

(5) Following the consultation with the European Financial Reporting Advisory Group, the Commission concludes that the amendment to IFRS 17 *Insurance Contracts* meets the criteria for adoption set out in Article 3(2) of Regulation (EC) No 1606/2002.

(6) Regulation (EC) No 1126/2008 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Accounting Regulatory Committee,

HAS ADOPTED THIS REGULATION:

Article 1

In the Annex to Regulation (EC) No 1126/2008, International Financial Reporting Standard (IFRS) 17 *Insurance Contracts* is amended as set out in the Annex to this Regulation.

([1]) OJ L 243, 11.9.2002, p. 1.

([2]) Commission Regulation (EC) No 1126/2008 of 3 November 2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council (OJ L 320, 29.11.2008, p. 1).

([3]) Commission Regulation (EU) 2021/2036 of 19 November 2021 amending Regulation (EC) No 1126/2008 adopting certain international accounting standards in accordance with Regulation (EC) No 1606/2002 of the European Parliament and of the Council as regards International Financial Reporting Standard 17 (OJ L 416, 23.11.2021, p. 3).

Article 2

Companies can apply the amendment referred to in Article 1 only on initial application of IFRS 17 *Insurance Contracts* and IFRS 9 *Financial Instruments*.

Article 3

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, 8 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Initial Application of IFRS 17 and IFRS 9 – Comparative Information

Amendment to IFRS 17

Amendment to IFRS 17 *Insurance Contracts*

Paragraphs C2A, C28A–C28E, C33A and the heading before paragraph C28A are added. For ease of reading these paragraphs have not been underlined.

Appendix C

Effective date and transition

...

EFFECTIVE DATE

...

C2A *Initial Application of IFRS 17 and IFRS 9—Comparative Information*, issued in December 2021, added paragraphs C28A–C28E and C33A. An entity that chooses to apply paragraphs C28A–C28E and C33A shall apply them on initial application of IFRS 17.

TRANSITION

...

Comparative information

...

Entities that first apply IFRS 17 and IFRS 9 at the same time

C28A An entity that first applies IFRS 17 and IFRS 9 at the same time is permitted to apply paragraphs C28B–C28E (classification overlay) for the purpose of presenting comparative information about a financial asset if the comparative information for that financial asset has not been restated for IFRS 9. Comparative information for a financial asset will not be restated for IFRS 9 if either the entity chooses not to restate prior periods (see paragraph 7.2.15 of IFRS 9), or the entity restates prior periods but the financial asset has been derecognised during those prior periods (see paragraph 7.2.1 of IFRS 9).

C28B An entity applying the classification overlay to a financial asset shall present comparative information as if the classification and measurement requirements of IFRS 9 had been applied to that financial asset. The entity shall use reasonable and supportable information available at the transition date (see paragraph C2(b)) to determine how the entity expects the financial asset would be classified and measured on initial application of IFRS 9 (for example, an entity might use preliminary assessments performed to prepare for the initial application of IFRS 9).

C28C In applying the classification overlay to a financial asset, an entity is not required to apply the impairment requirements in Section 5.5 of IFRS 9. If, based on the classification determined applying paragraph C28B, the financial asset would be subject to the impairment requirements in Section 5.5 of IFRS 9 but the entity does not apply those requirements in applying the classification overlay, the entity shall continue to present any amount recognised in respect of impairment in the prior period in accordance with IAS 39 *Financial Instruments: Recognition and Measurement*. Otherwise, any such amounts shall be reversed.

C28D Any difference between the previous carrying amount of a financial asset and the carrying amount at the transition date that results from applying paragraphs C28B–C28C shall be recognised in opening retained earnings (or other component of equity, as appropriate) at the transition date.

C28E An entity that applies paragraphs C28B–C28D shall:

(a) disclose qualitative information that enables users of financial statements to understand:

(i) the extent to which the classification overlay has been applied (for example, whether it has been applied to all financial assets derecognised in the comparative period);

(ii) whether and to what extent the impairment requirements in Section 5.5 of IFRS 9 have been applied (see paragraph C28C);

(b) only apply those paragraphs to comparative information for reporting periods between the transition date to IFRS 17 and the date of initial application of IFRS 17 (see paragraphs C2 and C25); and

(c) at the date of initial application of IFRS 9, apply the transition requirements in IFRS 9 (see Section 7.2 of IFRS 9).

...

C33A For a financial asset derecognised between the transition date and date of initial application of IFRS 17, an entity may apply paragraphs C28B–C28E (classification overlay) for the purpose of presenting comparative information as if paragraph C29 had been applied to that asset. Such an entity shall adapt the requirements of paragraphs C28B–C28E so that the classification overlay is based on how the entity expects the financial asset would be designated applying paragraph C29 at the date of initial application of IFRS 17.

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1492

of 8 September 2022

concerning the authorisation of L-valine produced by *Escherichia coli* CCTCC M2020321 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-valine produced by *Escherichia coli* CCTCC M2020321 as a feed additive for all animal species. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of L-valine produced by *Escherichia coli* CCTCC M2020321 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2022 ([2]) that, under the proposed conditions of use, L-valine produced by *Escherichia coli* CCTCC M2020321, when supplemented to diets in appropriate amounts, does not have an adverse effect on animal health, consumer safety or the environment. As regards the safety of the additive for the user, the Authority could not conclude on the potential of the additive to be toxic by inhalation, irritant to skin or eyes, or on its potential to be a dermal or a respiratory sensitiser, and noted that the endotoxin activity of the additive does not represent a hazard for users handling the additive. Furthermore, the Authority concluded that it is considered an efficacious source of the essential amino acid L-valine for animal nutrition and that in order to be efficacious in ruminants, the additive should be protected against degradation in the rumen. The Authority did not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) In view of the Authority's opinion, the Commission therefore 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 assessment of L-valine produced by *Escherichia coli* CCTCC M2020321 shows that the conditions for authorisation set out in Article 5 of Regulation (EC) No 1831/2003, are fulfilled.

(7) The use of this substance should therefore 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 2022;20(2):7163.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as a feed 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, 8 September 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/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c371ii	-	L-valine	*Additive composition* L-valine with a minimum content of 98 % (on a dry matter basis) and a maximum content of 1,5 % water. Powder form *Characterisation of the active substance* L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by *Escherichia coli* CCTCC M2020321 Chemical formula: $C_5H_{11}NO_2$ CAS number: 72-18-4 *Analytical method* [1]: For the identification of L-valine in the feed additive: — Food Chemical Codex 'L-valine monograph' For the quantification of valine in the feed additive: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS)	All species	-			1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixture shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 3. The label of the additive and premixture shall indicate the following: 'The supplementation with L-valine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.' 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks. Where risks cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment, including breathing, skin and eye protection.	29 September 2032

			For the quantification of valine in premixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of valine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS or IEC-VIS/FLD)						

(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) 2022/1493

of 8 September 2022

concerning the authorisation of L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) The application concerns the authorisation of L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 as feed additives for all animal species to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 March 2022 ([2]) that, under the proposed conditions of use, neither of the two products of L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 has an adverse effect on animal health, consumer health or the environment. As regards the safety of the user of that substance, the Authority concluded that the substance, in either products, is not an irritant to skin/eyes nor a dermal sensitiser and shows no toxicity by inhalation. However, the product L-methionine ≥ 90 % presents a risk to the user considering the exposure to endotoxins by inhalation. 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 that form of the substance.

(5) The Authority further concluded that L-methionine produced by *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 is an effective source of methionine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the substance should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of this substance 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.

(7) 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 2022;20(4):7247.

HAS ADOPTED THIS REGULATION:

Article 1

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues' are authorised as feed additives 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, 8 September 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	Mini-mum content	Maxi-mum content	Other provisions	End of period of authorisation
						mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c305	-	L-methionine	*Additive composition* L-methionine with a minimum content of 98,5 % and a maximum moisture content of 0,5 % Powder form *Characterisation of the active substance* L-methionine produced by fermentation with *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246 Chemical formula: $C_5H_{11}NO_2S$ CAS Number: 63-68-3. *Analytical methods* (1) For the determination of L-methionine in the feed additive: — Food Chemical Codex 'L-methionine monograph' and — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180	All species	-	-	-	1. L-methionine may be used via water for drinking. 2. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-methionine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.' 3. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. The endotoxin content of the additive and its dusting potential shall ensure that the maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air (3) is not exceeded.	29September 2032

			For the determination of methionine in premixtures — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 and — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 ([2]) (Annex III, F) For the determination of methionine in compound feed and feed materials: — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F) For the determination of methionine in water: — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)					5. 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 breathing protection.	
3c305ii	-	L-methionine	*Additive composition* Preparation of L-methionine with a minimum content of 90 % and a maximum moisture content of 0,5 % — other amino acids ≤ 0,63 %; Powder form *Characterisation of the active substance* L-methionine produced by fermentation with *Corynebacterium glutamicum* KCCM 80245 and *Escherichia coli* KCCM 80246	All species	-	-	-	1. L-methionine may be used via water for drinking. 2. The labelling of the additive and premixtures shall indicate the following: 'The supplementation with L-methionine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances.'	29 September 2032

			Chemical formula: $C_5H_{11}NO_2S$ CAS Number: 63-68-3.					3. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. The endotoxin content of the additive and its dusting potential shall ensure that the maximal endotoxin exposure of 1 600 IU endotoxins/m³ air (³) is not exceeded. 5. 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 breathing protection.	
			Analytical methods (¹) For the determination of L-methionine in the feed additive: — Food Chemical Codex 'L-methionine monograph' and — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 For the determination of methionine in premixtures — Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 and — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F) For the determination of methionine in compound feed and feed materials: — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Regulation (EC) No 152/2009 (Annex III, F) For the determination of methionine in water: — Ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)						

(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) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

(³) 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(10):5458); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2022/1494

of 7 September 2022

on the unresolved objections regarding the conditions for granting an authorisation for the biocidal product Mouskito Spray in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2022) 6264)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 36(3) thereof,

Whereas:

(1) On 19 October 2015, the company Laboratoria Qualiphar N.V./S.A. ('the applicant') submitted to the competent authorities of several Member States, including France, an application for mutual recognition in parallel, in accordance with Article 34 of Regulation (EU) No 528/2012, of the biocidal product Mouskito Spray ('the biocidal product'). The biocidal product is a ready-to-use product intended to protect human skin from insect bites and contains as active substance ethyl butylacetylaminopropionate (IR 3535). Belgium is the reference Member State responsible for the evaluation of the application as referred to in Article 34(1) of Regulation (EU) No 528/2012.

(2) The claims of the applicant for the product were: protection in areas with temperate climate against mosquitoes (*Aedes aegypti*, *Culex quinquefasciatus*), flies (*Stomoxys calcitrans*), bees (*Apis mellifera*), wasps (*Vespula vulgaris*), sandflies (*Phlebotomus*) and harvest mites (*Trombicula autumnalis*).

(3) On 11 July 2019, pursuant to Article 35(2) of Regulation (EU) No 528/2012, France referred objections to the coordination group, indicating that the biocidal product does not meet the condition laid down in Article 19(1), point (b)(i), of that Regulation for the use against bees and wasps. The referral was discussed in the coordination group on 16 September 2019.

(4) As no agreement was reached in the coordination group, on 7 November 2019 Belgium referred the unresolved objection to the Commission, pursuant to Article 36(1) of Regulation (EU) No 528/2012. Belgium provided the Commission with a detailed statement of the matter on which Member States were unable to reach agreement and the reasons for their disagreement. The statement was forwarded to the Member States concerned and to the applicant.

(5) France disagrees with the reference Member State's recommendation for authorisation of the use against wasps and bees. More specifically, France considers that efficacy for the specific use has not been demonstrated in the simulated-use test provided by the applicant, as the design of that test did not permit the determination of a complete protection time ([2]) and as the product was not applied on a human skin-like surface.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) The complete protection time is defined as the time between the repellent application and the time of two or more bites on the treated skin, or the first confirmed bite (a bite followed by another within 30 minutes).

(6) Belgium argues that the applicant has performed the tests required by the guidance existing at the time of the application submission and notes that for wasps and bees no established protocol exists. Belgium considers that a specific claim cannot be dismissed only because an established testing protocol does not exist and that therefore an expert judgement needs to be used. While acknowledging that no complete protection time was determined by the test provided by the applicant, Belgium concluded on the basis of expert judgement that the claim of repellence of bees and wasps was sufficiently supported.

(7) On 17 December 2021, the Commission requested an opinion on that matter from the European Chemicals Agency ('the Agency') in accordance with Article 36(2) of Regulation (EU) No 528/2012. The Agency was asked to indicate: (i) whether a determination of complete protection time is needed for the assessment of the efficacy against bees and wasps and whether the simulated-use test performed by the applicant allows the determination of a complete protection time; (ii) whether simulated-use tests should be performed on a human skin-like surface; and (iii) whether the performed simulated-use test generated data demonstrating that the biocidal product controls wasps and bees by repelling those organisms at the recommended dose and thereby support the claim 'repels wasps and bees'.

(8) On 2 March 2022, the Biocidal Products Committee of the Agency adopted its opinion ([3]).

(9) According to the Agency, efficacy data relevant to the actual conditions of use are needed to substantiate the product claims. The protection time is a very important parameter, especially for products intended to be used against dangerous insects, also considering that bees and wasps stings are a real concern to vulnerable individuals due to allergic reactions to the venom.

(10) The Agency acknowledges there are no agreed efficacy test protocols or criteria for topical repellents against wasps and bees and considers that it is the applicant's responsibility to provide efficacy data from studies designed to mimic the practical use situation in order to substantiate the claim.

(11) The tests performed by the applicant were field trials conducted in orchards. The repellent efficacy of the biocidal product was investigated using traps in the form of plastic bottles, filled with sugar solution and detergent to catch the target organisms. The surface of the traps was treated with the test product or remained untreated. According to the Agency, for repellents against bees and wasps the set-up of the test using traps with an attractant as test subject instead of humans could be acceptable, particularly due to ethical issues raised by exposure of humans to inevitable and painful bee and wasp stings. However, the data collected during the field trial performed by the applicant do not allow the establishment of the complete protection time.

(12) The Agency also points out that the surface of the bottles used as traps, which is a non-porous material, is significantly different from any material simulating the properties of human skin, especially in terms of absorbance and odour, which may affect the efficacy of the repellent. The test design should mimic the practical in-use situation as much as possible, for instance it would be preferable to use an absorbent human skin-like surface or texture like animal skin, or any artificial porous material modified in a way to simulate human skin.

(13) According to the Agency, the data submitted by the applicant from the field trials are in principle valid and could demonstrate the efficacy of products intended to be used as spatial or surface repellents and could substantiate a claim 'repels wasps and bees'. However, the test provided is not relevant for the intended use, that is topical repellent against wasps and bees to be applied on human skin and thus used to protect individuals against insect bites/stings. The generated data should be relevant to this intended use. The treated surface of the traps in the test performed does not sufficiently mimic the practical use situation, therefore the test design cannot be considered suitable to demonstrate efficacy of the product for the claimed use.

([3]) ECHA opinion ECHA/BPC/318/2022, https://echa.europa.eu/documents/10162/3443002/art_38_ethyl_butylacetylaminopropionate_bpc_opinion_en.pdf/1b489ec3-7868-2814-a3aa-a34557f4374d?t=1655449588766

(14) Taking into account the opinion of the Agency, the Commission considers that the biocidal product does not meet the condition laid down in Article 19(1), point (b)(i), of Regulation (EU) No 528/2012 for the use of the product as repellent against wasps and bees.

(15) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The biocidal product identified by the case number BC-SC020110-71 in the Register for Biocidal Products does not meet the condition laid down in Article 19(1), point (b)(i), of Regulation (EU) No 528/2012 for the use as repellent against wasps and bees.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 7 September 2022.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2022/1495

of 8 September 2022

postponing the expiry date of the approval of medetomidine for use in biocidal products of product-type 21 in accordance with Regulation (EU) No 528/2012 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) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Medetomidine was approved as an active substance for use in biocidal products of product-type 21 by Commission Implementing Regulation (EU) 2015/1731 ([2]) subject to the specifications and conditions set out in the Annex to that Regulation.

(2) The approval of medetomidine for use in biocidal products of product-type 21 ('the approval') is to expire on 31 December 2022. On 27 June 2021, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval ('the application').

(3) On 10 December 2021, the evaluating competent authority of Norway informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for the evaluation by the evaluating competent authority and for preparation and submission by the European Chemicals Agency of its opinion, and the time needed to decide whether the approval of medetomidine for use in biocidal products for product-type 21 may be renewed, the expiry date should be postponed to 30 June 2025.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) 2015/1731 of 28 September 2015 approving medetomidine as an active substance for use in biocidal products for product-type 21 (OJ L 252, 29.9.2015, p. 33).

(7) After the postponement of the expiry date of the approval, medetomidine remains approved for use in biocidal products of product-type 21 subject to the specifications and conditions set out in Implementing Regulation (EU) 2015/1731,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of medetomidine for use in biocidal products of product-type 21 set out in Implementing Regulation (EU) 2015/1731 is postponed to 30 June 2025.

Article 2

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

Done at Brussels, 8 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2022/1496

of 8 September 2022

postponing the expiry date of the approval of tebuconazole for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 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) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Tebuconazole was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-type 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved under that Regulation until 31 March 2020 subject to the requirements set out in Annex I to Directive 98/8/EC.

(2) On 27 September 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of tebuconazole for use in biocidal products of product-type 8 ('the application').

(3) On 6 February 2019, the evaluating competent authority of Denmark informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) The evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of Regulation (EU) No 528/2012. In that event, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.

(5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(6) Commission Implementing Decision (EU) 2019/1951 ([3]) postponed the expiry date of approval of tebuconazole for use in biocidal products of product-type 8 to 30 September 2022 in order to allow sufficient time for the examination of the application.

(7) On 3 May 2022, the evaluating competent authority informed the Commission that it expects to submit the renewal assessment report to the Agency in the first half of 2024.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([3]) Commission Implementing Decision (EU) 2019/1951 of 25 November 2019 postponing the expiry date of approval of tebuconazole for use in biocidal products of product-type 8 (OJ L 304, 26.11.2019, p. 21).

(8) Consequently, for reasons beyond the control of the applicant, the approval is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to enable the examination of the application. Taking into account the time-limits for evaluation by the evaluating competent authority, for preparation and submission by the Agency of its opinion and for the Commission to decide whether to renew the approval of tebuconazole for use in biocidal products for product-type 8, the expiry date should be postponed to 30 June 2026.

(9) After the postponement of the expiry date of the approval, tebuconazole remains approved for use in biocidal products of product-type 8 subject to the requirements set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of tebuconazole for use in biocidal products of product-type 8 set out in Implementing Decision (EU) 2019/1951 is postponed to 30 June 2026.

Article 2

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

Done at Brussels, 8 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2022/1497

of 8 September 2022

determining whether a product containing '*Capsicum* oleoresin expeller pressed' is a biocidal product, pursuant to Article 3(3) of Regulation (EU) No 528/2012 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) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 3(3) thereof,

Whereas:

(1) On 8 September 2021, Belgium requested the Commission to decide whether a product which contains, as indicated by the manufacturer, '*Capsicum* oleoresin expeller pressed' and is marketed in Belgium by the manufacturer as a repellent against cats and dogs ('the product'), is a biocidal product as defined in Article 3(1), point (a), of Regulation (EU) No 528/2012.

(2) According to the information provided by Belgium, the product is a spray for use on outdoor surfaces (such as terraces, paths, walls, fences, etc.) in order to deter cats and dogs from those surfaces. The intended use of the product is different from that of sprays containing the same or similar ingredients and intended to be used against aggressive animals for purposes of self-defence.

(3) In accordance with Article 3(2) of Regulation (EU) No 528/2012, the definition of 'substance' for the purposes of that Regulation is the one laid down in Article 3(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]), which defines a substance as a chemical element and its compounds in the natural state or obtained by any manufacturing process.

(4) According to the guidance of the European Chemicals Agency ([3]), whole living or unprocessed dead organisms or parts thereof (for instance, branches, fruits or flowers etc.) are not considered as substances within the meaning of Regulation (EC) No 1907/2006.

(5) '*Capsicum* oleoresin expeller pressed' is an oily organic resin obtained by expeller pressing from the fruits of plants of the *Capsicum* genus. Consequently, '*Capsicum* oleoresin expeller pressed' is made of compounds of chemical elements in the natural state, but is not a whole living or unprocessed dead organism or parts thereof.

(6) '*Capsicum* oleoresin expeller pressed' should therefore be considered as a substance within the meaning of Article 3(1) of Regulation (EC) No 1907/2006, and consequently, in accordance with Article 3(2), point (a), of Regulation (EU) No 528/2012, it should be considered also as a substance within the meaning of that Regulation.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

([3]) Guidance for Annex V - Exemptions from the obligation to register (see page 19), available at https://echa.europa.eu/documents/10162/2324906/annex_v_en.pdf/8db56598-f7b7-41ba-91df-c55f9f626545

(7) Under certain circumstances, cats and dogs may have an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce and, therefore, could fall within the definition of a harmful organism within the meaning of Article 3(1), point (g), of Regulation (EU) No 528/2012. Since '*Capsicum* oleoresin expeller pressed' contained in the product is intended to have an action against such harmful organisms, it is an active substance within the meaning of Article 3(1), point (c), of that Regulation.

(8) Given that the product contains an active substance and is intended to deter harmful organism by a mode of action that is not merely physical or mechanical, the product should be considered a biocidal product as defined in Article 3(1), point (a), of Regulation (EU) No 528/2012.

(9) Product-type 19, as defined in Annex V to Regulation (EU) No 528/2012, includes products used to control harmful organisms by repelling or attracting them. Since the product is used with the intention of repelling cats and dogs, such use falls under the description of product-type 19.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

A product containing '*Capsicum* oleoresin expeller pressed' used on outdoor surfaces for the purpose of repelling cats and dogs from those surfaces, shall be considered a biocidal product within the meaning of Article 3(1), point (a), of Regulation (EU) No 528/2012 and shall fall within product-type 19 as defined in Annex V to that Regulation.

Article 2

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

Done at Brussels, 8 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2022 OF THE JOINT COUNCIL ESTABLISHED BY THE ECONOMIC PARTNERSHIP AGREEMENT BETWEEN THE EUROPEAN UNION AND ITS MEMBER STATES, OF THE ONE PART, AND THE SADC EPA STATES, OF THE OTHER PART,

of 26 July 2022

on the adjustment of the reference quantities for certain products eligible for safeguard measures listed in Annex IV to the EU-SADC Economic Partnership Agreement [2022/1498]

THE JOINT COUNCIL,

Having regard to the Economic Partnership Agreement between the European Union and its Member States, of the one part, and the SADC EPA States, of the other part ('the Agreement'), and in particular Articles 35 and 102 thereof, and to Decision No 1/2019 of the Joint Council (Rules of Procedure of the Joint Council),

HAS ADOPTED THIS DECISION:

Article 1

In accordance with footnote 1 of Annex IV to the Agreement, the reference quantities set out in that Annex for the tariff lines indicated by an asterisk are adjusted, for the purposes of Article 35 of the Agreement, in accordance with the Annex to this Decision.

Article 2

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

Done at Brussels and Gaborone.

For the Joint Council

Representative of the SADC EPA States
Mmusi KGAFELA

EU representative
Valdis DOMBROVSKIS

ANNEX

ADJUSTED REFERENCE QUANTITIES AS REFERRED TO IN ARTICLE 1 OF THIS DECISION

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Tariff lines	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	Year 11	Year 12
0206 21 00	100	110	121	133	146	161	177	195	215	237	261	287
0206 29 00	1 005	1 106	1 206	1 307	1 407	1 508	1 609	1 709	1 810	1 910	2 011	2 111
0206 49 00	5 000	5 500	6 000	6 500	7 000	7 500	8 000	8 500	9 000	9 500	10 000	10 500
1104 19 10	150	165	182	200	220	242	266	293	322	354	390	429
1107 10 10	2 373	2 613	2 874	3 161	3 478	3 825	4 204	4 628	5 089	5 595	6 152	6 771
0401 20 07	6 353	6 986	7 701	8 457	9 315	10 234	11 256	12 379	13 625	14 973	16 485	18 119
2001 10 00	1 302	1 432	1 576	1 732	1 905	2 096	2 305	2 536	2 791	3 069	3 376	3 714
2001 90 10	270	297	328	360	396	436	480	527	580	638	701	771
1806 31	3 046	3 350	3 655	3 959	4 264	4 569	4 873	5 178	5 482	5 787	6 091	6 396
1806 32	938	1 032	1 126	1 220	1 314	1 408	1 501	1 595	1 689	1 783	1 877	1 971
1806 90	7 196	7 916	8 635	9 355	10 074	10 794	11 514	12 233	12 953	13 672	14 392	15 112

DECISION No 2/2022 OF THE JOINT COUNCIL ESTABLISHED UNDER THE ECONOMIC PARTNERSHIP AGREEMENT BETWEEN THE EUROPEAN UNION AND ITS MEMBER STATES, OF THE ONE PART, AND THE SADC EPA STATES, OF THE OTHER PART

of 26 July 2022

on the request from Angola pursuant to Article 119(1) of the EPA [2022/1499]

THE JOINT COUNCIL,

Having regard to the Economic Partnership Agreement between the European Union and its Member States, of the one part, and the SADC EPA States, of the other part ('the Agreement'), and in particular Articles 100, 101 and 119 thereof and to Article 8(4) of Decision 1/2019 of the Joint Council (Rules of Procedure of the Joint Council),

Recalling that Article 119(3) of the Agreement provides that the Parties agree that in the case of a request from Angola to the Joint Council to accede to the Agreement, negotiations concerning the terms of accession should be conducted on the basis of the Agreement, taking into account the specific situation of Angola,

HAS ADOPTED THIS DECISION:

Article 1

The Joint Council agrees to the request from Angola to start negotiations concerning the terms of its potential accession to the EU-SADC EPA pursuant to Article 119(1) of the EPA.

Article 2

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

Done at Brussels and Gaborone.

For the Joint Council

Representative of the SADC EPA States
Mmusi KGAFELA

EU representative
Valdis DOMBROVSKIS

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