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