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	-	Lemon essential oil	**Additive composition** Lemon essential oil from fruit peel of *Citrus limon* (L.) Osbeck Liquid form --- **Characterisation of the active substance:** Lemon essential oil derived 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): 0.5–3.0% Geranial: 0.1–2.0% Neral: 0.1–1.8% Perillaldehyde: ≤ 0.023% Furocoumarins: ≤ 0.2980 % Methoxycoumarins: ≤ 0,0570 % CAS 84929-31-7	Chickens for fatening	-		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 with other botanical additives is permitted provided that the amounts of perillalhedyde, 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 specie or animal category. 4. For users of the	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*
				Turkeys for fattening			40		
				Salmonids					
				Laying hens			52		
				Pigs for fattening			74		
				Piglets			62		
				Sows			92		
				Calves (milk replacers)			90		
				Cattle for fattening					
				Dairy cows					

[1] Natural sources of flavourings - Report No. 2 (2007)

			FEMA 2625 CoE No.: 139 --- **Analytical method**[2] For the quantification of d-limonene (phytochemical marker) in the feed additives (essential lemon oil): gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 855)	Horses Sheep/goats Rabbits			137 30	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.	
2b139- rf	-	Residual fraction from the distillation of lemon essential oil	**Additive composition** Residual fraction from the distillation of lemon essential oil from fruit peel of *Citrus limon* (L.) Osbeck Liquid form --- **Characterisation of the active substance:** Residual fraction from the distillation of lemon essential oil expressed which is obtained from fruit peel of *Citrus limon* (L.) Osbeck The specifications of the active substance are: d-Limonene: 51–63 %	Chickens for fattening Laying hens Turkeys for fatening Rabbits Salmonids Ruminants Piglets	-		11 12 20 20	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 with other botanical additives is permitted provided that the amounts of perillalhedyde, furocoumarins, and methoxycoumarins in feed materials and compound feed are lower than the one	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

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

			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: ≤ 0.7627.7 % Methoxycoumarins: ≤ 0.22 % CoE No.: 139 --- **Analytical method**[3] For the quantification of d-limonene (phytochemical marker) in the feed additives (residual fraction from the distillation of essential lemon oil): gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 855)	Pigs for fattening Sows Horses			24 30 35	resulting from the use of a single additive at the maximum or recommended level for the specie 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	
2b139-di	-	Distillate of lemon essential oil(volatile fraction)	**Additive composition** Distillate (volatile fraction) of lemon essential oil expressed, which is obtained from fruit peel of *Citrus limon* (L.) Osbeck Liquid form --- **Characterisation of the active substance.**	Chickens for fattening Laying hens Rabbits Turkeys for fatTening Piglets			36 53 56 48 64	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 with other botanical additives is	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

Kommenterede [RA(1]: Fefana request 2200
verification EFSA
As promised, I repeated the calculations with the higher values for citropten (see the new values highlighter in yellow) in tables 11, 15 and 16
As citropten counts for about 10% of total furocoumarins, the final conclusion doesn't change: we still have a 10-fold margin.
In addition, the assessment was very conservative, as we always used the maximum (the average is about the half) and we considered all furocoumarins as equipotent (as 5-MOP). In the reality, citropten is less potent (about 100 fold compared to 5-MOP).
I'm available for a call this morning.

Kommenterede [RA(2]: IO(VOLATILE FRACTION) dry-distilled essential oil
essential oil (2.11) obtained by distillation of wood, barks, roots or gums, without addition of water or steam

coe

[3] 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

			Distillate (volatile fraction) from lemon essential oil expressed, which is obtained from fruit peel of *Citrus limon* (L.) Osbeck as defined by the Council of Europe[4] 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 No.: 139 --- **Analytical method[5]** For the quantification of d-limonene (phytochemical marker) in the feed additives (distillate fraction of essential lemon): gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 855)	Pigs for fattening Sows Calves (milk replacers) Cattle for fattening Sheep/goats Horses Dairy cows Salmonids Ornamental fish Dogs Cats			76 94 95 141 91 60 30	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.	
2b141-eo		Lime essential oil	**Additive composition** Lime essential oil obtained by steam distillation from unpeeled fruits of the plant species *Citrus aurantiifolia*	Chickens for fattening Laying hens Turkeys for			8.5 12.5 11	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use	*[10 years from the date of entry into force of this Regulation.*

[4] Natural sources of flavourings - Report No. 2 (2007)

[5] 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

			(Christm.) Swingle Liquid form --- **Characterisation of the active substance.** 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[6] The specifications of the active substance are: d-Limonene: 45–52 % γ-Terpinene: 10–14 % Terpinolene: 5.5–10.5% αTerpineo: l 6–8% β-Caryophyllene: 0.2–0.8% Furocoumarins: ≤ 0.0083 % Methoxycoumarins: ≤ 0.0282.3 % CoE .No.:141 --- **Analytical method[7]** For the quantification of d-limonene (phytochemical marker) in the feed additives (lime essential oil): gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 855)	fatening Piglets Pigs for fattening Sows Cattle for fattening Calves (milk replacers) Dairy cows Sheep/goats Horses Rabbits Salmonids			 15 18 22 33.5 35.5 21.5 33.5 13.5 30	of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. Mixture with other botanical additives is permitted provided that the amounts of perillalhedyde, 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 specie 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	*To be completed by the OP]*

[6] Natural sources of flavourings - Report No. 2 (2007)

[7] 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

								protective equipment, including skin, eye and breathing protection.	