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Safety and efficacy of a feed additive consisting of an essential oil derived from the aerial parts of *Cymbopogon flexuosus* (Nees ex Steud.) Will. Watson (lemongrass oil) for use in all animal species (FEFANA asbl)

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of lemongrass oil obtained from the aerial parts of *Cymbopogon flexuosus* (Nees ex Steud.) Will. Watson when used as a sensory additive for all animal species. The FEEDAP Panel concluded that lemongrass oil is safe up to the maximum proposed use levels in complete feed of 125 mg/kg for salmonids; 100 mg/kg for sows and horses; 75 mg/kg for veal calves (milk replacer), cattle for fattening, dairy cows, sheep and goats; and 50 mg/kg for dogs and ornamental fish. For the other species, the calculated safe concentrations in complete feed were 41 mg/kg for chickens for fattening, 61 mg/kg for laying hens, 55 mg/kg for turkeys for fattening, 74 mg/kg for piglets, 88 mg/kg for pigs for fattening, 65 mg/kg for rabbits and 33 mg/kg for cats. These conclusions were extrapolated to other physiologically related species. For any other species, the additive is safe at 33 mg/kg complete feed. The use of lemongrass oil in water for drinking for poultry, pigs, calves and rabbit is safe provided that the total daily intake does not exceed the daily amount considered safe when consumed via feed. No concerns for consumers and the environment were identified following the use of the additive up to the highest safe use level in feed. The essential oil under assessment should be considered as an irritant to skin and eyes and as a dermal and respiratory sensitiser. Since the aerial parts of *C. flexuosus* and its preparations were recognised to flavour food and its function in feed would be essentially the same as that in food, no further demonstration of efficacy was considered necessary.

Keywords: sensory additives, flavouring compounds, *C. flexuosus*, lemongrass oil, neral, geranial, safety

Requestor: European Commission

Question number: EFSA-Q-2010-01282 (new EFSA-Q-2023-00396)

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1. Introduction

1.1. Background and terms of reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7. In addition, Article 10(2) of that Regulation specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, within a maximum of 7 years after the entry into force of this Regulation.

The European Commission received a request from Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)[2] for authorisation/re-evaluation of 18 preparations (namely geranium oil, geranium rose oil, eucalyptus oil, eucalyptus tincture, clove oil, clove tincture, broom tea tree oil, purple loosestrife tincture, tea tree oil, melaleuca cajuputi oil, niaouli oil, allspice oil, bay oil, pomegranate bark extract, bambusa tincture, citronella oil, lemongrass oil and vetiveria oil) belonging to botanically defined group (BDG) 07 – *Geraniales, Myrtales, Poales* when used, when used as a feed additive for all animal species (category: sensory additives; functional group: flavourings). During the assessment, the applicant withdrew the application for six preparations (namely broom tea tree oil, geranium oil, bay oil and vetiveria oil[3]; bambusa tincture and allspice oil[4]). These preparations were deleted from the register of feed additives.[5] During the course of the assessment, this application was split, and the present opinion covers only one out of the remaining 12 preparations under application: lemongrass oil from *Cymbopogon flexuosus* (Nees ex Steud.) Will. Watson.[6] for all animal species.

The remaining 11 preparations belonging to botanically defined group (BDG) 07 – *Geraniales, Myrtales, Poales* under application are assessed in separate opinions.

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority deleted (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 21 December 2010.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of lemongrass oil from *C. flexuosus* (aerial parts - fresh or dry), when used under the proposed conditions of use (see Section 3.2.4).

1.2. Additional information

Lemongrass oil from *C. flexuosus* is currently authorised as a feed additive according to the entry in the European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 (2b natural products – botanically defined). It has not been assessed as a feed additive in the EU.

There is no specific EU authorisation for any *C. flexuosus* preparation when used to provide flavour in food. However, according to Regulation (EC) No 1334/2008[7] flavouring preparations produced from food, may be used without an evaluation and approval as long as 'they do not, on the basis of the

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] On 13/03/2013, EFSA was informed by the applicant that the applicant company changed to FEFANA asbl, Avenue Louise 130 A, Box 1, 1050 Brussels, Belgium.
[3] On 27 February 2019, EFSA was informed by the applicant about the withdrawal of the applications on broom teatree oil, geranium oil, bay oil and vetiveria oil.
[4] On 18 November 2022, EFSA was informed by the EC about the withdrawal of the applications on nabbusa tincture and allspice oil.
[5] Register of feed additives, Annex II, withdrawn by OJ L162, 10.05.2021, p. 5.
[6] Accepted name: *Cymbopogon flexuosus* (Nees ex Steud.) Will. Watson; synonyms: *Cymbopogon flexuosus* (Nees ex Steud.) W. Watson; *Cymbopogon flexuosus* (Nees ex Steudel) J.F. Watson.
[7] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Regulation (EC) No 1601/91 of the Council, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34.

scientific evidence available, pose a safety risk to the health of the consumer, and their use does not mislead the consumer'.

Lemongrass oil form *C. flexuosus* is described in a monograph of the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2004).

Many of the individual components of the essential oil have been already assessed as chemically defined flavourings for use in feed and food by the FEEDAP Panel, the EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC), the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and the EFSA Panel on Food Additives and Flavourings (FAF) and/or the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The flavouring compounds currently authorised for feed[8] and/or food[9] use, together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000[10] and the corresponding EFSA opinion are listed in Table 1.

Table 1: Flavouring compounds already assessed by EFSA as chemically defined flavourings, grouped according to the chemical group (CG) as defined in Commission Regulation (EC) No 1565/2000, with indication of the EU Flavour Information System (FLAVIS) number and the corresponding EFSA opinion

CG	Chemical Group	Product (EU register name)	FLAVIS No	EFSA* or JECFA opinion, Year
01	Straight-chain primary aliphatic alcohols/ aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes	Octanal	05.009	2013
		Decanal	05.010	
		Dodecanal	05.011	
		Methyl geranate	09.643	2011a, CEF
03	a, ß-Unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/ acids, acetals and esters	Geraniol	02.012	2016a
		(*Z*)-Nerol	02.058	
		Neral	05.170	
		trans-3,7-Dimethylocta-2,6-dienal (geranial)	05.188	
		Geranic acid	08.081	
		Geranyl acetate	09.011	
		Geranyl butyrate	09.048	
		Neryl formate	09.212	
		Neryl acetate	09.213	
04	Non-conjugated and accumulated unsaturated straight-chain and branched-chain aliphatic primary alcohols, aldehydes, acids, acetals and esters	Citronellol	02.011	2016b
		Hex-3(cis)-en-1-ol	02.056	
		Citronellal	05.021	
		2,6-Dimethylhept-5-enal	05.074	
		Citronellyl formate	09.078	
05	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols	Heptan-2-one	07.002	2015a
		6-Methyhept-5-en-2-one	07.015	2015a
		Heptan-4-one[(a)]	07.058	WHO, 1999 JECFA
		Nonan-4-one	07.189	2017, CEF

[8] European Union Register of Feed Additives pursuant to Regulation (EC) No 1831/2003. Available online: https://ec.europa.eu/food/sites/food/files/safety/docs/animal-feed-eu-reg-comm_register_feed_additives_1831-03.pdf

[9] Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC. OJ L 267, 2.10.2012, p. 1.

[10] Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council. OJ L 180, 19.7.2000, p. 8.

CG	Chemical Group	Product (EU register name)	FLAVIS No	EFSA* or JECFA opinion, Year
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool	02.013	2012a
		α-Terpineol	02.014	
		4-Terpinenol	02.072	
		α-(−)-Elemol[(a)]	02.149	2011b, CEF 2015a, CEF
07	Primary alicyclic saturated and unsaturated alcohols/aldehydes/acids/acetals/esters with esters containing alicyclic alcohols	(1R,2R,5S) 5-Isopropenyl-2-methylcyclopentanecarboxaldehyde	05.123	2008a, EFSA (AFC)
08	Secondary alicyclic saturated and unsaturated alcohols, ketones, ketals and esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols	Menthol	02.015	2016c
		d,l-Borneol	02.016	
		p-Menth-1-en-3-one[(a)]	07.175	2011c, CEF
		Carveol[(a)]	02.062	2015b, CEF
		(Z)-Verbenol (pin-2-en-4-ol)	02.101	2011c, CEF
10	Secondary aliphatic saturated or unsaturated alcohols, ketones, ketals and esters with a second secondary or tertiary oxygenated functional group	4-Hydroxy-4-methylpentan-2-one	07.165	2011d, CEF
14	Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms	3-Methyl-2(3-methylbut-2-enyl)furan (rose furan)	13.148	2015c, CEF 2021a,b FAF
17	Propenylhydroxybenzenes	Isoeugenol[(b)]	04.004	2012d
31	Aliphatic and aromatic hydrocarbons and acetals containing saturated aldehydes	Limonene[(a),(c)]	01.001	2008b, EFSA
		1-Isopropyl-4-methylbenzene (p-Cymene)	01.002	2015b
		Terpinolene	01.005	
		Pin-2(10)-ene (β-pinene)	01.003	2016d
		Pin-2(3)-ene (α-pinene)	01.004	
		β-Caryophyllene	01.007	
		Myrcene	01.008	
		Camphene	01.009	
		cis-3,7-Dimethyl-1,3,6-octatriene cis-β-Ocimene[(a)]	01.064	
		β-Cubebene[(a),(d)]	01.030	2011e, CEF
		Germacra-1(10),4(14),5-triene (δ-Germacrene)[(a),(d)]	01.042	
		3,7,10-Humulatriene[(a),(d)]	01.043	
		1,1,7-trimethyltricyclo [2.2.1.0.(2.6)] heptane (tricyclene)[(a),(d)]	01.060	
		β-Ocimene[(e)] (3,7-Dimethyl-1,3,6-octatriene)	01.018	2015d, CEF
		β-Bourbonene[(a)]	01.024	
32	Epoxides	β-Caryophyllene epoxide[(a)]	16.043	2014, CEF

*: FEEDAP opinion unless otherwise indicated.
(a): Evaluated for use in food. According to Regulation (EC) 1565/2000, flavourings evaluated by JECFA before 2000 are not required to be re-evaluated by EFSA.
(b): EFSA evaluated isoeugenol [04.004], a mixture of *(E)*- and *(Z)*-isomers (EFSA FEEDAP Panel, 2012d).
(c): JECFA and EFSA evaluated d-limonene [01.045] (EFSA, 2008b). d-Limonene [01.045] and l-limonene [01.046] were also evaluated for use in feed (EFSA FEEDAP Panel, 2015b).
(d): Evaluated applying the 'Procedure' described in the Guidance on the data required for the risk assessment of flavourings to be used in or on food (EFSA CEF Panel, 2010). No longer authorised for use as flavours in food, as the additional toxicity data requested (EFSA CEF Panel, 2011c) were not submitted and the CEF Panel was unable to complete its assessment.
(e): EFSA evaluated β-ocimene [01.018], a mixture of *(E)*- and *(Z)*-isomers (EFSA CEF Panel, 2015d).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[11] in support of the authorisation request for the use of lemongrass oil from *C. flexuosus* as a feed additive. The dossier was received on 8 June 2023 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00396.[12]

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports and experts' knowledge, to deliver the present output.

Many of the components of the essential oil under assessment have been already evaluated by the FEEDAP Panel as chemically defined flavourings (CDGs). The applicant submitted a written agreement to reuse the data submitted for the assessment of chemically defined flavourings (dossiers, publications and unpublished reports) for the risk assessment of preparations belonging to BDG 07, including the current one under assessment.[13]

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the phytochemical markers in the additive. The evaluation report is related to the methods of analysis for each feed additive included in the group BDG 07 (Geraniales, Myrtales, Poales). During the assessment, upon request from EFSA, the EURL issued a first amendment of the original report, which included the additive under assessment, *lemongrass oil*.[14] In particular, the EURL recommended a method based on gas chromatography with flame ionisation detection (GC-FID) for the quantification of the phytochemical markers *trans-3,7-dimethylocta-2,6-dienal* (hereinafter referred to as geranial) and *neral* in lemongrass oil.[15]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of lemongrass oil from *C. flexuosus* is in line with the principles laid down in Regulation (EC) No 429/2008[16] and the relevant guidance documents: Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (EFSA SC, 2009), Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern (EFSA, 2009), Guidance for the preparation of dossiers for sensory additives (EFSA FEEDAP Panel, 2012b), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012c), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA SC, 2019a), Statement on the genotoxicity assessment of chemical mixtures (EFSA SC, 2019b), Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA SC, 2019c).

3. Assessment

The additive under assessment, lemongrass oil, is an essential oil obtained from the aerial parts (fresh or dry) from *C. flexuosus*, intended for use as a sensory additive (functional group: flavouring compounds) in feed and in water for drinking for all animal species.

[11] Dossier reference: FAD-2010-0219.
[12] The original application EFSA-Q-2010-01282 was split on 08/06/2023 and a new EFSA-Q-2023-00396 was generated.
[13] Technical dossier/Supplementary information February 2023/Letter dated 31/01/2023.
[14] Preparations included in the first amendment: geranium rose oil, eucalyptus oil, lemongrass oil and clove oil.
[15] The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0219_en
[16] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

3.1. Origin and extraction

There are two species of *Cymbopogon* that are commonly described as lemongrass. *Cymbopogon flexuosus* (Nees ex Steud.) Will Watson is referred to as East-Indian lemongrass or sometimes Cochin or Malabar grass, while *Cymbopogon citratus* Stapf. is referred to as West-Indian lemongrass or citronella grass. Both species are tufted, evergreen perennial grasses belonging to the Poaceae family, and both originated in India. They can be and are used interchangeably as culinary or medicinal herbs, sharing similar properties and the same lemon-scent. However, *C. citratus* is generally favoured for culinary purposes, while *C. flexuosus* is preferred by the perfume industry because of its higher extraction yields.

The essential oil is extracted by steam distillation from dry or fresh aerial parts of *C. flexuosus*. The volatile constituents are condensed and then separated from the aqueous phase by decantation.

3.2. Characterisation

3.2.1. Characterisation of lemongrass oil

The essential oil under assessment is a pale yellow to yellowish brown liquid with a strong odour resembling that of citral. Lemongrass oil is identified with the single Chemical Abstracts Service (CAS) number 8007-02-1,[17] the European Inventory of Existing Commercial Chemical Substances (EINECS) number 289-752-0, the Flavor Extract Manufacturers Association (FEMA) number 2624[18] and the Council of Europe (CoE) number 38.

For lemongrass oil, the product specifications used by the applicant are based on those developed by the International Organization for Standardization; ISO 4718:2004 for oil of lemongrass (*Cymbopogon flexuosus*),[19] which were adapted to reflect the concentrations of selected volatile components. Five components contribute to the specifications as shown in Table 2, with neral and geranial selected as the phytochemical markers. The analysis of six batches of the additive showed compliance with these specifications when analysed by gas chromatography–mass spectrometry (GC–MS) and expressed as percentage of gas chromatographic peak area (% GC area).[20] The applicant provided the full characterisation of the volatile constituents in six batches obtained by GC–MS.[21] The five compounds indicated in the product specifications accounted for about 84.6% on average (range 81.7–86.2%) of % GC area (Table 2).

Table 2: Major constituents of the essential oil from the aerial parts (fresh or dry) of *Cymbopogon flexuosus* (Nees ex Steud.) Will. Watson as defined by specifications: batch to batch variation based on the analysis of six batches by gas chromatography–mass spectrometry (GC–MS). The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%

Constituent	CAS No	FLAVIS No	% GC area		
EU register name			Specification[(a)]	Mean	Range
trans-3,7-Dimethylocta-2,6-dienal (Geranial)	141-27-5	05.188	35–47	40.35	38.46–45.00
Neral	106-26-3	05.170	25–35	31.63	29.92–33.66
Geraniol	106-24-1	02.012	1.5–8	6.47	3.31–7.86
Geranyl acetate	105-87-3	09.011	0.5–6	4.45	3.94–5.22

[17] CAS No. 8007-02-1 is applied to the essential oil from either *C. flexuosus* or *C. citratus*. CAS No. 91844–92-7 covers all extracts of *C. flexuosus*, including the essential oil under assessment.
[18] FEMA 2624 refers to essential oils from *C. flexuosus* and *C. citratus*
[19] Technical dossier/Supplementary information January 2023/Annex III_SIn_reply_lemongrass_oil_ISO_4718_2004.
[20] Technical dossier/Supplementary information January 2023/SIn_reply_lemongrass_oil_Table 3.
[21] Technical dossier/Supplementary information January 2023 Annex_II_SIn_reply_lemongrass_oil_CoAs_chromatograms

Constituent EU register name	CAS No	FLAVIS No	% GC area		
			Specification[(a)]	Mean	Range
β-Caryophyllene	87-44-5	01.007	0.2–3.5	1.75	1.07–2.47
Total				84.64	81.73–86.15[(b)]

EU: European Union; CAS No: Chemical Abstracts Service number; FLAVIS No: EU Flavour Information System numbers.
(a): Specifications defined based on GC-FID analysis.
(b): The values given for the total are the lowest and the highest values of the sum of the components in the batches analysed.

In total, up to 81 peaks were detected in the chromatogram, 80 of which were identified and accounted on average for 99.27% (98.65–100%) of the % GC area. Besides the five compounds indicated in the product specifications, 10 other compounds were detected at individual levels > 0.5% and are listed in Table 3. These 15 compounds together account on average for 93.33% (91.78–94.15%) of the % GC area. The remaining 66 compounds, accounting on average for 5.95% of the % GC area (ranging between 4.83% and 6.87%), are listed in the footnote.[22] Based on the available data on the characterisation, lemongrass oil is considered a fully defined mixture (EFSA SC, 2019a).

Table 3: Constituents of the essential oil from the aerial part of *Cymbopogon flexuosus* (Nees ex Steud.) Will. Watson, accounting for > 0.5% of the composition (based on the analysis of six batches) not included in the specifications. The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%

Constituent EU register name	CAS No	FLAVIS No	% GC area	
			Mean	Range
6-Methylhept-5-en-2-one	110-93-0	07.015	1.51	0.96–2.05
γ-Cadinene	39029-41-9	–	1.40	0.39–2.00
Linalool	78-70-6	02.013	1.18	0.89–1.50
Camphene	79-92-5	01.009	1.14	0.83–1.64
4-Nonanone	4485-09-0	07.189	1.05	0.27–1.55
(Z)-Verbenol	1845-30-3	02.101	0.79	0.42–1.16
(E)-isocitral	72203-98-6	–	0.70	0.66–0.75
Limonene	138-86-3	01.001	0.58	0.24–1.87
β-Caryophyllene epoxide	1139-30-6	16.043	0.56	0.39–0.62
(+)-δ-Cadinene	483-76-1		0.51	0.29–0.77
Total			8.69	6.68–11.12[(a)]

EU: European Union; CAS No: Chemical Abstracts Service number; FLAVIS No: EU Flavour Information System number.
(a): The values given for the total are the lowest and the highest values of the sum of the components in the batches analysed.

The applicant performed a literature search for the chemical composition of *C. flexuosus* and its preparations to identify the presence of any recognised substances of concern.[23] The applicant consulted the online database on volatile compounds in food (VCF).[24] One reference (Taskinen et al., 1983) reported the presence of trace amounts of methyleugenol and elemicin in the essential oil from *C. flexuosus* obtained by a different manufacturing process. The same authors also reported

[22] Additional constituents:constituents (n = 17) between < 0.5 and ≥ 0.2%: (E)-isoeugenol, 3,7-dimethyl-3,6-octadienal, 2,2-dimethyl-3,4-octadienal, β-ocimene, cis-limonene epoxide, (Z)-isocitral, (1S,2S,5R)-2-isopropenyl-5-methyl-cyclopentanecarbaldehyde, cyclosativene, (Z)-nerol, (Z)-isoeugenol, geranic acid, citronellal, α-terpineol, α-pinene, (E)-γ-bisabolene, 3,7,10-humulatriene and borneol;constituents (n = 20) between < 0.2 and ≥ 0.1%: menthol, carveol, rose furan epoxide, (Z)-γ-bisabolene, (-)-trans-isopiperitenol, germacra-1(10),4(14),5-triene, p-menth-1-en-3-one, (1R,2R,5S) 5-isopropenyl-2-methylcyclopentane carboxaldehyde, 4-epi-cubebol, cis-3,7-dimethyl-1,3,6-octatriene, 2,10-epoxypinane, tricyclene, α-copaene, β-elemene, d-8-p-menthene-1,2-epoxide, neryl formate, cubebol, 3-methyl-2(3-methylbut-2-enyl)furan, decanal and α-cadinene;constituents (n = 29) between < 0.1 and ≥ 0.01%: geranyl butyrate, citronellol, phellandral, (-)-α-elemol, 2,3-dihydro-1,8-cineole, myrcene, terpinolene, humulene oxide II, 4-terpinenol, octanal, methyl geranate, β-cubebene, p-mentha-1,3,8-triene, β-bourbonene, 2-cyclohexene-1-acetaldehyde, α,2-dimethyl-5-(1-methylethenyl), 4-hydroxy-4-methylpentan-2-one, exo-isocitral, 2,6-dimethylhept-5-enal, dodecanal, p-cymene, α-cubebene, β-pinene, citronellyl formate, β-copaene, neryl acetate, heptan-4-one, hex-3(cis)-en-1-ol and heptan-2-one.
[23] Technical dossier/Supplementary information January 2023/Literature search_lemongrass_oil.
[24] https://www.vcf-online.nl/VcfHome.cfm

higher amounts of methyleugenol (20%) to be present in lemongrass oil obtained from certain chemotypes of *C. flexuosus*, in oils rich in sesquiterpenes such as isointermedeol, borneol and bisabolol, characterised by different composition compared to the additive under assessment (Taskinen et al., 1983). The EMA reported methyleugenol levels at 77.6–82.4% in essential oils from the whole plant of *Cymbopogon flexuosus* (Nees ex Steud.) W. Watson (EMA HMPC, 2005). Methyleugenol and elemicin were not detected by GC–MS in the essential oil under assessment (limit of detection, LOD 0.01%).

3.2.2. Impurities

The applicant referred to the 'periodic testing' of some representative flavourings premixtures for mercury, cadmium, lead, arsenic, fluoride, dioxins and polychlorinated biphenyls (PCBs), organochloride pesticides, organophosphorous pesticides, aflatoxins (B1, B2, G1, G2) and ochratoxin A. However, no data were provided on the presence of these impurities. Since lemongrass oil is produced by steam distillation, the likelihood of any measurable carry-over of all the above-mentioned elements is considered low, except for mercury.

3.2.3. Shelf-life

The typical shelf-life of lemongrass oil is stated to be at least 12 months, when stored in tightly closed containers under standard conditions (in a cool, dry place protected from light).[25] However, no data supporting this statement were provided.

3.2.4. Conditions of use

Lemongrass oil is intended to be added to feed for all animal species without a withdrawal period. Maximum use levels in complete feed were proposed for the animal species and categories listed in Table 4. No use level has been proposed by the applicant for the other target species. The applicant proposed that the additive may be added in water for drinking at 10 mg/kg for poultry, pigs, calves and rabbits.

Table 4: Conditions of use for the essential oil from the aerial parts of *Cymbopogon flexuosus* (Nees ex Steud.) Will. Watson: maximum proposed use levels in complete feed for the different target species

Animal category	Maximum use level (mg/kg complete feed)
Chicken for fattening	75
Laying hen	75
Turkey	75
Piglet	100
Pig for fattening	100
Sow	100
Veal calf (milk replacers)	75
Cattle for fattening	75
Dairy cow	75
Sheep/goat	75
Horse	100
Rabbit	100
Fish (salmon)	125
Dog	50
Cat	50
Ornamental fish	50

3.3. Safety

The assessment of safety of lemongrass oil is based on the maximum use levels proposed by the applicant in complete feed for the species listed above (see Table 4).

[25] Technical dossier/Section II.

Many of the components of lemongrass oil, accounting for about 96% of the GC peak areas, have been previously assessed and considered safe for use as flavourings, and are currently authorised for use in food[9] without limitations and for use in feed[8] at individual use levels higher than those resulting from the intended use of the essential oil in feed. The list of compounds already evaluated by the EFSA Panels is given in Table 1 (see Section 1.2).

Four compounds listed in Table 1, β-cubebene [01.030], germacra-1(10),4(14),5-triene [10.042], 3,7,10-humulatriene [01.043] and tricyclene [01.060], have been evaluated in Flavouring Group Evaluations (reference to FGE.25Rev2) by applying the procedure described in the Guidance on the data required for the risk assessment of flavourings to be used in or on foods (EFSA CEF Panel, 2010). For these compounds, for which there is no concern for genotoxicity, EFSA requested additional subchronic toxicity data (EFSA CEF Panel, 2011e). In the absence of such toxicological data, the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015e). As a result, these compounds are no longer authorised for use as flavours in food. For these compounds, in the absence of toxicity data, the FEEDAP Panel applies the threshold of toxicological concern (TTC) approach or read-across from structurally related substances, as recommended in the Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA SC, 2019a).

Thirty-one compounds have not been previously assessed for use as flavourings. The FEEDAP Panel notes that 18 of them[26] accounting for 5.4% of the GC–MS area are aliphatic mono- or sesquiterpenes structurally related to flavourings already assessed in CG 4, 6, 8 and 31 and for which a similar metabolic and toxicological profile is expected. Because of their lipophilic nature, they are expected to be rapidly absorbed from the gastro-intestinal tract, oxidised to polar oxygenated metabolites, conjugated and excreted (EFSA FEEDAP Panel, 2012a, 2015b, 2016b,c,d). Five additional components (rose furan epoxide, humulene oxide II, 2,10-epoxypinane, cis-limonene epoxide and d-8-p-menthene-1,2-epoxide) are metabolites of terpenes and seven components (3,7-dimethyl-3,6-octadienal, 2-cyclohexene-1-acetaldehyde, α,2-dimethyl-5-(1-methylethenyl)-, (1S,2S,5R)-2-isopropenyl-5-methyl-cyclopentanecarbaldehyde, phellandral, 2,3-dehydrocineole, *(Z)*- and *(E)*-methyl isoeugenol) are structurally related to compounds that have been evaluated for use in food and/or feed.

The remaining compound (2,2-dimethyl-3,4-octadienal) was screened with the Organisation for Economic Co-operation and Development (OECD) QSAR Toolbox. Structural alerts for *in vitro* mutagenicity were identified due to the presence of an aldehyde. For 2,2-dimethyl-3,4-octadienal, predictions of mutagenicity by Ames test (with and without S9) were made by 'read-across' analyses of data available for similar substances to the target compounds (i.e. analogues obtained by categorisation). Mutagenicity read-across-based predictions were found negative for all the substances.[27] On this basis, the alerts raised were discounted.

3.3.1. Safety for the target species

Tolerance studies in the target species and/or toxicological studies in laboratory animals made with the essential oil under application were not submitted.

In the absence of these data, the approach to the safety assessment of a mixture whose individual components are known is based on the safety assessment of each individual component (component-based approach). This approach requires that the mixture is sufficiently characterised and that the individual components can be grouped into assessment groups, based on structural and metabolic similarity. The combined toxicity can be predicted using the dose addition assumption within an assessment group, taking into account the relative toxic potency of each component (EFSA SC, 2019a).

As the additive under assessment is a fully defined mixture (the identified components represent > 99.3% of the % GC area, see Section 3.2.1), the FEEDAP Panel applied a component-based approach to assess the safety for target species of the essential oil.

Based on considerations related to structural and metabolic similarities, the components were allocated to 13 assessment groups, corresponding to chemical groups (CGs) 1, 3, 4, 5, 6, 7, 8, 10, 14, 16, 17, 31 and 32, as defined in Annex I of Regulation (EC) No 1565/2000. For chemical group 31 ('aliphatic and aromatic hydrocarbons'), subassessment groups as defined in Flavouring Group Evaluation 25 (FGE.25) and FGE.78 were established (EFSA CEF Panel, 2015d,e). The allocation of the components to the (sub-)assessment groups is shown in Table 5 and in the corresponding footnote.

[26] exo-Isocitral, (Z)-isocitral, (E)-isocitral (CG 4); 4-epi-cubebol, cubebol (CG 6); (Z)-verbenol, (-)-trans-isopiperitenol (CG 8); p-mentha-1,3,8-triene, (E)-γ-bisabolene, (Z)-γ-bisabolene, β-copaene, cyclosativene, α-copaene, β-cubebene, γ-cadinene, (+)-δ-cadinene, α-cubebene, α-cadinene (CG 31).

[27] Technical dossier/Supplementary information January 2023/Annex VI_SIn_reply_lemongrass_oil_QSAR.

For each component in the assessment group, exposure of target animals was estimated considering the use levels in feed, the percentage of the component in the oil and the default values for feed intake according to the guidance on the safety of feed additives for target species (EFSA FEEDAP Panel, 2017b). Default values on body weight are used to express exposure in terms of mg/kg bw per day. The intake levels of the individual components calculated for chickens for fattening, the species with the highest ratio of feed intake/body weight per day, are shown in Table 5.

For hazard characterisation, each component of an assessment group was first assigned to the structural class according to Cramer classification (Cramer et al., 1978). For some components in the assessment groups, toxicological data were available to derive no observed adverse effect levels (NOAEL) values. Structural and metabolic similarity among the components in the assessment groups were assessed to explore the application of read-across, allowing extrapolation from a known NOAEL of a component of an assessment group to the other components of the group with no available NOAEL or, if sufficient evidence were available for members of a (sub-)assessment group, to derive a (sub-)assessment group NOAEL.

Toxicological data of subchronic studies, from which NOAEL values could be derived, were available for acetaldehyde [05.001] the representative compound in CG 1 (EFSA FEEDAP Panel, 2013), citral [05.020] the representative compound in CG 3 (EFSA FEEDAP Panel, 2016a), citronellol [02.011], hex-3(cis)-en-1-ol [02.056] and 2,6-dimethylhept-5-enal [05.074] in CG 4 (EFSA FEEDAP Panel, 2016b), for heptan-2-one [07.002] and 6-methylhept-5-en-2-one [07.015] in CG 5 (EFSA FEEDAP Panel, 2015a), terpineol [02.230][28] and linalool [02.013] in CG 6 (EFSA FEEDAP Panel, 2012a), menthol [02.015] in CG 8 (EFSA FEEDAP Panel, 2016c), isoeugenol [04.004] in CG 17 (EFSA FEEDAP Panel, 2012d), myrcene [01.008], d-limonene [01.045], p-cymene [01.002] and β-caryophyllene in CG 31 (EFSA FEEDAP, 2015b, 2016d), and β-caryophyllene epoxide [16.043] for CG 32 (EFSA CEF Panel, 2014). For d-carvone [01.146] and 2-pentylfuran [13.059], not present in the essential oil but structurally related to some components, the applicant made reference to a BMD lower confidence limit for a benchmark response of 10% ($BMDL_{10}$) of 60 mg/kg bw per day (EFSA SC, 2014; EFSA FEEDAP Panel, 2016c) and of 8.52 mg/kg bw per day (EFSA FAF Panel, 2021a,b), respectively.

The NOAEL of 120 mg/kg bw per day for acetaldehyde [05.001] was selected as reference point for CG 1 compounds and the NOAEL of 345 mg/kg bw per day for citral [05.020] was used as a group NOAEL for all compounds belonging to CG 3 and for the structurally related aldehydes in CG 4, namely 3,7-dimethyl-3,6-octadienal, exo-isocitral, (Z)-isocitral and (E)-isocitral (EFSA FEEDAP Panel, 2021).

Considering the structural and metabolic similarities, the NOAEL of 50 mg/kg bw per day for citronellol [02.011] was applied using read-across to citronellal [05.021] and citronellyl formate [09.078] in CG 4.

In CG 5, the NOAEL of 20 mg/kg bw per day for heptan-2-one [07.002] was applied to heptan-4-one [07.058] and 4-nonanone [07.189].

The NOAEL of 250 mg/kg bw per day available for terpineol [02.230] and d-limonene [01.045] was selected as a reference point for the structurally similar terpinyl derivatives α-terpineol [02.014] and 4-terpinenol [02.072] in CG 6, as well as (Z)-verbenol [02.101] and (-)-trans-isopiperitenol in CG 8.

The NOAEL of 34 mg/kg bw per day for deca-2(trans),4(trans)-dienal [05.140] was extrapolated using read-across to phellandral in CG 7 (EFSA FEEDAP Panel, 2022).

In CG 8, the NOAEL of 15 mg/kg bw per day of d,l-isobornyl acetate [09.218] was extrapolated to borneol [02.016] and carveol [02.062] and the $BMDL_{10}$ of 60 mg/kg bw per day for d-carvone [07.146] to p-menth-1-en-3-one [07.175].

The $BMDL_{10}$ of 8.51 mg/kg bw per day derived 2-pentylfuran [13.059] was applied to 3-menthyl-2 (3-methylbut-2-enyl)furan [13.148] in CG 14.

For the isoeugenol (Z)- and (E)-stereoisomers in CG 17, the NOAEL of 75 mg/kg bw per day for isoeugenol was applied.

The NOAELs of 44 and 222 mg/kg bw per day for the representative compounds in CG 31, myrcene [01.008] and β-caryophyllene [01.007] were applied using read-across to the compounds within subassessment group II (β-ocimene and cis-3,7-dimethyl-1,3,6-octatriene) and V (γ-cadinene, camphene, (+)-δ-cadinene, cyclosativene, α-pinene, tricyclene, α-copaene, α-cadinene, α-cubebene, β-bourbonene, β-cubebene, β-copaene, β-pinene),[29] respectively (EFSA CEF Panel, 2015d,e).

[28] Terpineol is a mixture of four isomers: α-terpineol [02.014], a mixture of *(R)*-(+)-α-terpineol and *(S)*-(−)-α-terpineol, β-terpineol, γ-terpineol and 4-terpinenol [02.072].

[29] Some of these compounds are not listed in Table 5 because their individual margin of exposure (MOE) was >50,000.

The NOAEL of 109 mg/kg bw per day for β-caryophyllene epoxide [16.043] was used for humulene oxide II, 2,10-epoxypinane, cis-limonene epoxide and d-8-p-menthene-1,2-epoxide in CG 32. A NOAEL of 8.51 mg/kg bw per day for rose furan epoxide was extrapolated from 3-methyl-2(3-methylbut-2-enyl)furan (rosefuran).

For the remaining compounds,[30] toxicity studies performed with the compounds under assessment and NOAEL values derived from toxicity studies were not available and read-across was not possible. Therefore, the threshold of toxicological concern (TTC) approach was applied (EFSA FEEDAP Panel, 2012b, 2017b). All these compounds belong to Cramer class I, except 2,3-dehydro-1,8-cineole (Cramer class II).

As a result of the hazard characterisation, a reference point was identified for each component in the assessment group based on the toxicity data available (NOAEL from *in vivo* toxicity study or read-across) or from the 5th percentile of the distribution of NOAELs of the corresponding Cramer Class (i.e. 3, 0.91 and 0.15 mg/kg bw per day, respectively, for Cramer Class I, II and III compounds; Munro et al., 1996). Reference points selected for each compound are shown in Table 5.

For risk characterisation, the margin of exposure (MOE) was calculated for each component as the ratio between the reference point and the exposure. For each assessment group, the combined (total) margin of exposure (MOET) was calculated as the reciprocal of the sum of the reciprocals of the MOE of the individual substances (EFSA SC, 2019a). An MOET > 100 allowed for interspecies- and intra-individual variability (as in the default 10 × 10 uncertainty factor). The compounds resulting individually in an MOE > 50,000 were not further considered in the assessment group as their contribution to the MOE(T) is negligible. They are listed in the footnote.[31]

The approach to the safety assessment of lemongrass oil for the target species is summarised in Table 5. The calculations were done for chickens for fattening, the species with the highest ratio of feed intake/body weight and represent the worst-case scenario at the use level of 75 mg/kg in feed.

Table 5: Compositional data, intake values (calculated for chickens for fattening at 75 mg/kg complete feed), reference points and margin of exposure (MOE) for the individual components of lemongrass oil classified according to assessment groups

Essential oil composition			**Exposure**		**Hazard characterisation**		**Risk characterisation**	
Assessment group	**FLAVIS No**	**Highest conc. in the oil**	**Highest feed conc.**	**Intake[(a)]**	**Cramer Class[(b)]**	**NOAEL[(c)]**	**MOE**	**MOET**
Constituent	–	**%**	**mg/kg**	**mg/kg bw per day**	–	**mg/kg bw per day**	–	–
CG 1								
Decanal	05.010	0.16	0.120	0.0108	(I)	120	11,139	
Octanal	05.009	0.10	0.075	0.0067	(I)	120	17,823	
Methyl geranate	09.643	0.06	0.048	0.0043	I	*3*	696	
MOET CG 1								625
CG 3								
Geranial	05.188	45.00	33.750	3.0298	(I)	345	114	
Neral	05.170	33.66	25.245	2.2663	(I)	345	152	
Geraniol	02.012	7.86	5.895	0.5292	(I)	345	652	
Geranyl acetate	09.011	5.22	3.915	0.3515	(I)	345	982	
(Z)-Nerol	02.058	0.65	0.488	0.0438	(I)	345	7,883	
Neryl formate	09.212	0.32	0.240	0.0215	(I)	345	16,013	
Geranic acid	08.081	0.30	0.228	0.0205	(I)	345	16,855	

[30] Methyl geranate (CG 1); 2,2-Dimethyl-3,4-octadienal (CG 4), 4-epi-cubebol, cubebol and (-)-alpha-elemol [02.149] (CG 6); 2-Cyclohexene-1-acetaldehyde, alpha,2-dimethyl-5-(1-methylethenyl), (1R,2R,5S) 5-Isopropenyl-2-methylcyclopentanecarboxaldehyde [05.123], (1S,2S,5R)-2-isopropenyl-5-methyl-cyclopentanecarbaldehyde (CG 7); 4-Hydroxy-4-methylpentan-2-one [07.165] (CG 10); 2,3-dihydro-1,8-cineole (CG 16); beta-elemene (CG 31, III); 3,7,10-Humulatriene [01.043] and germacra-1(10),4(14),5-triene [01.042] (CG 32).

[31] Dodecanal (CG 1); neryl acetate (CG 3); exo-isocitral, hex-3(cis)-en-1-ol (CG 4); 4-terpinenol (CG 6); p-cymene (CG 31, IV); β-copaene, β-cubebene, α-cubebene, β-bourbonene (CG 31, V).

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS No**	**Highest conc. in the oil**	**Highest feed conc.**	**Intake[a]**	**Cramer Class[b]**	**NOAEL[c]**	**MOE**	**MOET**
Constituent	–	**%**	**mg/kg**	**mg/kg bw per day**	–	**mg/kg bw per day**	–	–
Geranyl butyrate	09.048	0.14	0.105	0.0094	(I)	345	36,600	
MOET CG 3								55
CG 4								
(E)-Isocitral	–	0.75	0.560	0.0503	(I)	345	6,860	
3,7-dimethyl-3,6-octadienal	–	0.66	0.495	0.0444	(I)	345	7,764	
2,2-Dimethyl-3,4-octadienal	–	0.54	0.405	0.0364	I	*3*	83	
(Z)-Isocitral	–	0.37	0.274	0.0246	(I)	345	14,038	
Citronellal	05.021	0.24	0.176	0.0158	(I)	50	3,160	
Citronellol	02.011	0.17	0.128	0.0114	(I)	**50**	4,368	
Citronellyl formate	09.078	0.06	0.045	0.0040	(I)	50	12,377	
2,6-Dimethylhept-5-enal	05.074	0.04	0.029	0.0026	(I)	**37**	14,461	
MOET CG 4								76
CG 5								
6-Methylhept-5-en-2-one	07.015	2.05	1.538	0.1380	(II)	**50**	362	
4-Nonanone	07.189	1.55	1.162	0.1043	(II)	20	192	
Heptan-4-one	07.058	0.02	0.015	0.0013	(I)	20	14,852	
Heptan-2-one	07.002	0.02	0.013	0.0011	(I)	**20**	17,473	
MOET CG 5								123
CG 6								
Linalool	02.013	1.45	1.123	0.1008	(I)	**117**	1,161	
α-Terpineol	02.014	0.40	0.300	0.0269	(I)	250	9,283	
(−)-α-Elemol	02.149	0.21	0.158	0.0141	I	*3*	212	
Cubebol	–	0.19	0.143	0.0128	I	*3*	235	
4-epi-cubebol	–	0.16	0.117	0.0105	I	*3*	286	
MOET CG 6								74
CG 7								
(1S,2S,5R)-2-Isopropenyl-5-methyl-cyclopentanecarbaldehyde	–	0.38	0.286	0.0257	I	*3*	117	
(1R,2R,5S) 5-Isopropenyl-2-methylcyclopentanecarboxaldehyde	05.123	0.12	0.148	0.0133	I	*3*	226	
Phellandral	–	0.14	0.105	0.0094	(I)	34	3,607	
2-Cyclohexene-1-acetaldehyde, α,2-dimethyl-5-(1-methylethenyl)-	–	0.05	0.035	0.0031	I	*3*	969	
MOET CG 7								70
CG 8								
(Z)-Verbenol	02.101	1.16	0.870	0.0781	(I)	250	3,201	
p-Menth-1-en-3-one	07.175	0.49	0.368	0.0330	(II)	60	1,819	
Borneol	02.016	0.32	0.242	0.0217	(I)	15	692	
(-)-trans-Isopiperitenol	–	0.31	0.233	0.0209	(I)	250	11,978	
Carveol	02.062	0.26	0.195	0.0175	(I)	15	857	
Menthol	02.015	0.19	0.143	0.0129	(I)	**375**	29,160	
MOET CG 8								278
CG 10								
4-Hydroxy-4-methylpentan-2-one	07.165	0.05	0.038	0.0034	I	*3*	891	
CG 14								
3-Methyl-2(3-methylbut-2-enyl)furan	13.148	0.13	0.100	0.0090	(II)	8.51	950	

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS No**	**Highest conc. in the oil**	**Highest feed conc.**	**Intake[a]**	**Cramer Class[b]**	**NOAEL[c]**	**MOE**	**MOET**
Constituent	–	**%**	**mg/kg**	**mg/kg bw per day**	–	**mg/kg bw per day**	–	–
CG 16								
2,3-Dehydro-1,8-cineole	–	0.10	0.077	0.0069	II	*0.91*	133	
CG 17								
(E)-Isoeugenol	–	0.46	0.348	0.0312	(I)	75	2,401	
(Z)-Isoeugenol	–	0.35	0.263	0.0236	(I)	75	3,183	
MOET CG 17								1,368
CG 31, II								
β-Ocimene	01.018	0.55	0.412	0.0370	(I)	44	1,190	
cis-3,7-Dimethyl-1,3,6-octatriene	01.064	0.21	0.158	0.0141	(I)	44	3,112	
Myrcene	01.008	0.09	0.067	0.0060	(I)	**44**	7,343	
MOET CG 31, II								771
CG 31, III								
d-Limonene	01.001	1.87	1.403	0.1259	(I)	250	1,986	
(Z)-γ-Bisabolene	–	0.27	0.203	0.0182	(I)	250	13,752	
b-Elemene	–	0.23	0.173	0.0155	I	*3*	194	
(E)-γ-Bisabolene	–	0.23	0.171	0.0154	(I)	250	16,285	
Terpinolene	01.005	0.11	0.083	0.0074	(I)	250	33,755	
p-Mentha-1,3,8-triene		0.08	0.060	0.0054	(I)	250	46,414	
MOET CG 31, III								171
CG 31, IV								
p-Cymene	01.002	0.04	0.033	0.0030	(I)	**154**	51,983	
CG 31, V								
β-Caryophyllene	01.007	2.47	1.853	0.1663	(I)	**222**	1,335	
γ-Cadinene	–	1.20	1.497	0.1344	(I)	222	1,652	
Camphene	01.009	1.64	1.231	0.1105	(I)	222	2,009	
(+)-δ-Cadinene		0.77	0.578	0.0518	(I)	222	4,282	
Cyclosativene	–	0.51	0.383	0.0343	(I)	222	6,465	
α-Pinene	01.004	0.32	0.243	0.0218	(I)	222	10,177	
Tricyclene	01.060	0.20	0.153	0.0137	(I)	222	16,163	
α-Copaene	–	0.17	0.125	0.0112	(I)	222	19,863	
α-Cadinene	–	0.16	0.120	0.0108	(I)	222	20,608	
MOET CG 31, V								390
CG 31, VI								
3,7,10-Humulatriene	01.043	0.28	0.210	0.0189	I	*3*	159	
Germacra-1(10),4(14),5-triene	01.042	0.22	0.166	0.0149	I	*3*	202	
MOET CG 31, VI								89
CG 32								
cis-Limonene epoxide	–	0.77	0.578	0.0518	(I)	109	2,102	
β-Caryophyllene epoxide	16.043	0.62	0.467	0.0419	(III)	**109**	2,603	
2,10-Epoxypinane		0.25	0.188	0.0168	(I)	109	6,476	
Rose furan epoxide	–	0.24	0.177	0.0159	(III)	8.51	536	
d-8-p-Menthene-1,2-epoxide	–	0.16	0.120	0.0108	(I)	109	10,118	
Humulene oxide II	–	0.07	0.050	0.0044	(III)	109	24,529	
MOET CG 32								331
Unknown	–	0.11	0.080	0.0071				

(a): Intake calculations for the individual components are based on the use level of 5 mg/kg in feed for chickens for fattening, the species with the highest ratio of feed intake/body weight. The MOE for each component is calculated as the ratio of the reference point (NOAEL) to the intake. The combined margin of exposure (MOET) is calculated for each assessment group as the reciprocal of the sum of the reciprocals of the MOE of the individual substances.
(b): When a NOAEL value is available or read-across is applied, the allocation to the Cramer class is put into parentheses.
(c): values **in bold** refer to those components for which the NOAEL value was available, values *in italics* are the 5th percentile of the distribution of NOAELs of the corresponding Cramer Class, other values (plain text) are NOAELs extrapolated by using read-across.

As shown in Table 5, for several assessment groups, the MOET was < 100 at the proposed use levels of the additive (see Table 4). The lowest MOET was calculated for CG 3, the assessment group which includes the major components geranial and neral. From the lowest MOET of 55 for chickens for fattening, the MOET for CG 3 compounds was calculated for the other target species considering the respective daily feed intake and conditions of use. The results are summarised in Table 6.

Table 6: Combined margin of exposure (MOET) for the assessment group CG 3 calculated for the different target animal categories at the proposed use level and maximum safe use level in feed calculated to ensure an MOET ≥ 100 (500 for cats)

Animal category	Body weight (kg)	Feed intake (g DM/day)	Proposed use level (mg/kg feed)[(a)]	Lowest MOET CG 3	Maximum safe use level (mg/kg feed)[(a)]
Chicken for fattening	2	158	75	55	41
Laying hen	2	106	75	82	61
Turkey for fattening	3	176	75	74	55
Piglet	20	880	100	74	74
Pig for fattening	60	2,200	100	88	88
Sow lactating	175	5,280	100	109	100
Veal calf (milk replacer)	100	1,890	75	229	75
Cattle for fattening	400	8,000	75	217	75
Dairy cows	650	20,000	75	140	75
Sheep/goat	60	1,200	75	217	75
Horse	400	8,000	100	163	100
Rabbit	2	100	100	65	65
Salmon	0.12	2.1	125	145	125
Dog	15	250	50	383	50
Cat[(b)]	3	60	50	326	33
Ornamental fish	0.012	0.054	50	1,304	50

(a): Complete feed containing 88% DM, milk replacer 94.5% DM.
(b): The MOET for cats is increased to 500 because of the reduced capacity of glucuronidation.

At the proposed use levels in complete feed, the MOET exceeds the value of 100 for sows, veal calves, cattle for fattening, dairy cows, sheep, goats, horses, salmons, dogs and ornamental fish. For the other species, the maximum safe use levels in feed were calculated to ensure an MOET ≥ 100. Because glucuronidation is an important metabolic pathway to facilitate the excretion of the components of the essential oil and considering that cats have an unusually low capacity for glucuronidation (Court and Greenblatt, 1997; Lautz et al., 2021), the use of lemongrass oil as additive in cat feed needs a wider margin of exposure. An MOET of 500 is considered adequate. The maximum safe levels in feed are shown in Table 6.

In poultry, pigs and rabbits, the daily consumption of water by drinking is about two to three times the amount of feed DM ingested (EFSA FEEDAP Panel, 2017a). The applicant proposed a maximum use level of 10 mg/kg water for drinking for poultry, pigs, calves and rabbits, which would ensure a comparable or lower exposure to the calculated maximum safe use level in feed. In veal calves, the use of the additive at 10 mg/kg water can be considered safe only when added to the water for drinking but not to the water used to prepare the milk replacer.

The FEEDAP Panel considers that for poultry, pigs, calves and rabbits, the use in water for drinking alone or in conjunction with use in feed should not exceed the daily amount that is considered safe when consumed via feed alone.

3.3.1.1. Conclusions on safety for the target species

The conclusions of the FEEDAP Panel on the maximum safe concentrations in complete feed of lemongrass oil are summarised in Table 7.

Table 7: Maximum safe concentrations of lemongrass oil in complete feed (mg/kg) for all animal species and categories

Animal categories	Maximum safe concentration (mg/kg feed)[(a)]
Chickens for fattening, other poultry for fattening or reared for laying/ reproduction, ornamental birds and other avian species at the same physiological stage	41
Laying hens and other laying/reproductive birds	61
Turkeys for fattening	55
Pigs for fattening	88
Piglets and other Suidae species for meat production or reared for reproduction	74
Sows and other Suidae species for reproduction	100
Veal calves (milk replacer)	75
Sheep/goat	75
Cattle for fattening, other ruminants for fattening or reared for milk production/reproduction and camelids at the same physiological stage	75
Dairy cows and other ruminants and camelids for milk production or reproduction	75
Horses and other Equidae	100
Rabbits	65
Salmonids and minor fin fish	125
Dogs	50
Cats	33
Ornamental fish	50
Any other species	33

(a): Complete feed containing 88% DM, milk replacer 94.5% DM.

The FEEDAP Panel considers for poultry, pigs, calves and rabbits that the use in water for drinking alone or in combination with use in feed should not exceed the daily amount that is considered safe when consumed via feed alone.

3.3.2. Safety for the consumer

Lemongrass and lemongrass oil are added to a wide range of food categories for flavouring purposes. Although individual consumption figures are not available, the Fenaroli's handbook of flavour ingredients (Burdock, 2009) cites daily exposure values of 0.002 mg/kg per day for lemongrass oil from either *C. flexuosus* (Need ex Steud.) J.F Watson or *C. citratus* (DC. ex Nees) Stapf (FEMA 2624). Fenaroli's handbook reports use levels (in mg/kg) of 9.42–14.11 in frozen dairy, 21.14–33.26 in soft candy, 27.27–36.32 in baked goods, 12.56–19.11 in gelatines and puddings, 138.80–197.00 in chewing gum, 6.55–8.94 in alcoholic beverages, 5.45–5.45 in fats and oils, 0.01–0.01 in hard candy, 5.85–8.99 in non-alcoholic beverages and 1.00–1.60 in meat products.

Many of the individual constituents of the essential oil under assessment are currently authorised as food flavourings without limitations and have been already assessed for consumer safety when used as feed additives in animal production (see Table 1, Section 1.2).

No data on residues in products of animal origin were made available for any of the constituents of the essential oil. However, the Panel recognises that the constituents of lemongrass oil are expected to be extensively metabolised and excreted in the target species. Consequently, relevant residues in food products are unlikely.

Considering the above and the reported human exposure due to the direct use of lemon grass, lemongrass oil and its preparations in food (Burdock, 2009), it is unlikely that the consumption of products from animals given lemongrass oil at the proposed maximum use level would increase human background exposure.

No safety concern would be expected for the consumer from the use of lemongrass oil up to the highest safe use level in feed for the target animals.

3.3.3. Safety for the user

No specific data were provided by the applicant regarding the safety of the additive for users.

The applicant provided a safety data sheet[32] for lemongrass oil, where hazards for users have been identified.

The applicant made a literature search aimed at retrieving studies related to the safety of preparations obtained from *C. flexuosus* for the users.[33] There is limited evidence from the literature of skin irritation (Opdyke, 1979) and skin sensitisation in mice due to the citral component (Lalko and Api, 2006; reviewed by Tisserand and Young, 2014).

The FEEDAP Panel concludes that lemongrass oil should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser.

3.3.4. Safety for the environment

C. flexuosus is not a species native to Europe. Therefore, the safety for the environment is assessed based on the individual components of the essential oil.

The major components (geranial, neral, geraniol, geranyl acetate and β-caryophyllene) and additional 28 components (see Table 1) accounting together for about 91.5% of the composition of the oil have been evaluated by EFSA as sensory additives for animal feed. At the maximum proposed use level for chickens for fattening of 75 mg/kg complete feed, the concentration in feed of the two major components, geranial and neral would be up to 33.6 and 25.2 mg/kg, respectively. These values are above the level of 25 mg/kg which was considered safe for citral, a mixture of geranial and neral, in the opinion on CG 3 (EFSA FEEDAP Panel, 2016a). For citral, the applicant provided data on the natural occurrence in citrus fruit up to 130 mg/kg.[34] Therefore, no risk to the environment is expected for the two major components. Concerning the other components evaluated as feed additives, they were considered to be safe for the environment at individual use levels higher than those resulting from the use of the essential oil in feed (see Table 1, Section 1.2).

The remaining identified constituents of the essential oil, which were not evaluated for use in feed, are chemically related to the substances evaluated by EFSA in CG 1, 4, 5, 6, 8 and 31 (EFSA FEEDAP Panel, 2012a, 2013, 2015a,b, 2016b,c, 2021), for which EFSA concluded that they were extensively metabolised by the target species (see Section 3.3.1) and excreted as innocuous metabolites or carbon dioxide. Therefore, no risk to the safety of the environment is foreseen. For rose furan epoxide, β-caryophyllene epoxide and humulene oxide II, the applicant provided evidence on the natural occurrence in plants native to Europe.[35]

The use of the additive in animal feed under the proposed conditions of use is not expected to pose a risk to the environment.

3.4. Efficacy

Lemongrass oil from *C. flexuosus* is listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2009) and by FEMA with the reference number 2624.

[32] Technical dossier/Supplementary information January 2023/Annex VII_SIn_reply_lemongrass_MSDS. Hazard for eye irritation/ eye damage (H318, category 1), skin corrosion/irritation (H315, category 2), skin sensitisation (H317, category 1) in accordance with the criteria outlined in Annex I of 1272/2008/EC (CLP/EU-GHS).

[33] Technical dossier/Supplementary information January 2023/Literature search_lemongrass oil.

[34] FAD-2010-0124_CDG_03/Supplementary information August 2011/Annexes/Annex_TNO_2011_FL-05.020.

[35] Technical dossier/Supplementary information January 2023/SIn_reply_lemongrass oil

Since the aerial parts of *C. flexuosus* and its preparations are recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary.

4. Conclusions

Lemongrass oil from the aerial parts of *Cymbopogon flexuosus* (Nees ex Steud) Will. Watson may be produced from plants with different chemical compositions resulting in preparations of different composition. Thus, the following conclusions apply only to lemongrass oil in which methyleugenol and elemicin are not detected, and for which geranial and neral are the main constituents.

The conclusions of the FEEDAP Panel on the maximum safe concentrations in complete feed of lemongrass oil are summarised as follows:

Animal categories	Maximum safe concentration (mg/kg feed)[(a)]
Chickens for fattening, other poultry for fattening or reared for laying/ reproduction, ornamental birds and other avian species at the same physiological stage	41
Laying hens and other laying/reproductive birds	61
Turkeys for fattening	55
Pigs for fattening	88
Piglets and other Suidae species for meat production or reared for reproduction	74
Sows and other Suidae species for reproduction	100
Veal calves (milk replacer)	75
Sheep/goat	75
Cattle for fattening, other ruminants for fattening or reared for milk production/reproduction and camelids at the same physiological stage	75
Dairy cows and other ruminants and camelids for milk production or reproduction	75
Horses and other Equidae	100
Rabbits	65
Salmonids and minor fin fish	125
Dogs	50
Cats	33
Ornamental fish	50
Any other species	33

(a): Complete feed containing 88% DM, milk replacer 94.5% DM.

The FEEDAP Panel considers for poultry, pigs, calves and rabbits that the use in water for drinking alone or in combination with use in feed should not exceed the daily amount that is considered safe when consumed via feed alone.

No concerns for consumers were identified following the use of the additive at the maximum proposed use level in feed.

The essential oil under assessment should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser.

The use of the additive under the proposed conditions in animal feed is not expected to pose a risk to the environment.

Since the aerial parts of *C. flexuosus* and their essential oil are recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary.

5. Recommendation

The specification should ensure that methyleugenol and elemicin are not detected in lemongrass oil from *Cymbopogon flexuosus* (Nees ex Steud) Will. Watson.

6. Documentation provided to EFSA/chronology

Date	Event
28/10/2010	Dossier received by EFSA. Botanically defined flavourings from Botanical Group 07 – Geraniale, Myrtales, Poales for all animal species and categories. Submitted by Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)
09/11/2010	Reception mandate from the European Commission
21/12/2010	Application validated by EFSA – Start of the scientific assessment
22/03/2011	Comments received from Member States
01/04/2011	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: analytical methods*
08/01/2013	Reception of supplementary information from the applicant - Scientific assessment remains suspended
26/02/2013	EFSA informed the applicant (EFSA ref. 7150727) that, in view of the workload, the evaluation of applications on feed flavourings would be re-organised by giving priority to the assessment of the chemically defined feed flavourings, as agreed with the European Commission
20/01/2014	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
24/06/2015	Technical hearing during risk assessment with the applicant according to the "EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products": data requirement for the risk assessment of botanicals
17/12/2019	EFSA informed the applicant that the evaluation process restarted
18/12/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation, safety for target species, safety for the consumer, safety for the user and environment*
31/01/2023	Reception of supplementary information from the applicant (partial dataset: lemongrass oil) - Scientific assessment remains suspended
06/06/2023	Reception of an amendment of the Evaluation report of the European Union Reference Laboratory for Feed Additives related to geranium rose oil, eucalyptus oil, lemongrass oil and clove oil
07/06/2023	The application was split and a new EFSA-Q-2023-00396 was assigned to the preparation included in the present assessment
08/06/2023	Scientific assessment re-started for the preparation included in the present assessment
04/07/2023	Opinion adopted by the FEEDAP Panel on lemongrass oil (EFSA-Q-2023-00396). End of the Scientific assessment for the preparation included in the present assessment. The assessment of other preparations in BGD 07 is still ongoing

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Abbreviations

AFC	EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
BW	Body weight
BDG	Botanically defined group
CAS	Chemical Abstracts Service
CD	Commission Decision
CDG	Chemically defined group
CEF	EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CG	chemical group
CoE	Council of Europe
DM	dry matter
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Chemical Substances
EMA	European Medicines Agency
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FFAC	Feed Flavourings authorisation Consortium of FEFANA (EU Association of Specialty Feed Ingredients and their Mixtures)
FEMA	Flavour Extract Manufacturers Association
FGE	food group evaluation
FLAVIS	The EU Flavour Information System
FL-no	FLAVIS number
GC–MS	Gas chromatography–mass spectrometry

GC-FID	Gas chromatography-flame ionisation detection
ISO	International Organisation for Standardisation
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOD	Limit of detection
MOE	Margin of Exposure
MOET	Total Margin of Exposure
NOAEL	No observed adverse effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
SCF	Scientific Committee on Food
TTC	Threshold of toxicological concern
UF	Uncertainty factor
VCF	Volatile Compounds in Food
WHO	World Health Organization
QSAR	Quantitative Structure Activity Relationship