SCIENTIFIC OPINION

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Safety and efficacy of a feed additive consisting of an essential oil obtained from the fruit of *Coriandrum sativum* L. (coriander oil) (FEFANA asbl)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of an essential oil obtained from the fruit of *Coriandrum sativum* L. (coriander oil), when used as a sensory additive in feed for all animal species. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that the use of coriander oil is safe up to the maximum proposed use levels of 30 mg/kg complete feed for piglets, pigs for fattening, sows, veal calves (milk replacer), cattle for fattening, sheep, goats and horses, salmonids, dogs and ornamental fish. For the other species, the calculated safe concentrations in complete feed are: 14 mg/kg for chickens for fattening, 28 mg/kg for laying hens, 26 mg/kg for turkeys for fattening, 28 mg/kg for rabbits and 14 mg/kg for cats. These conclusions were extrapolated to physiologically related species. For any other species, the additive was considered safe at 14 mg/kg complete feed. The proposed conditions of use for veal calves (10 mg/kg) and ruminants, horses and dogs (5 mg/kg) were considered safe provided that the use in water for drinking alone or in combination with the use in feed should not exceed the daily amount that is considered safe when consumed via feed alone. No concerns for consumers and the environment were identified following the use of coriander oil up to the maximum proposed use level in feed. Coriander oil should be considered as irritant to skin and eyes and the respiratory tract and as a dermal and respiratory sensitiser. Since *C. sativum* and its preparations are 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, coriander oil, *Coriandrum sativum* L., linalool, safety, component-based approach

Requestor: European Commission

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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 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 29 preparations (namely dill herb oil, dill seed extract, dill tincture, dong quai tincture, celery seed oil, celery seed extract (oleoresin), celery tincture, hares ear tincture, caraway seed oil, caraway oleoresin/extract, coriander oil, cumin oil, taiga root extract (solvent-based, sb), taiga root tincture, fennel oil, fennel tincture, common ivy extract (sb), opoponax oil, ginseng tincture, parsley oil, parsley tincture, anise oil, anise tincture, ajowan oil, Ferula Assa-foetida oil, anise star oil, anise star tincture, anise star terpenes and omicha tincture) belonging to botanically defined group (BDG) 02 – *Apiales/ Austrobaileyales* when used as feed additives for all animal species (category: sensory additives; functional group: flavourings). During the assessment, the applicant withdrew the application for nine preparations (dill seed extract, celery seed extract (oleoresin), caraway oleoresin/extract, opoponax oil,[3] parsley oil, hares ear tincture, taiga root extract (sb), ajowan oil[4] and parsley tincture[5]). During the course of the assessment, this application was split and the present opinion covers only one out of the 20 remaining preparations under application: coriander oil from the fruit of *Coriandrum sativum* L. The remaining 19 preparations belonging to botanically defined group (BDG) 2 -Apiales and Austrobaileyales 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 (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 3 January 2011.

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 product coriander oil (*C. sativum*), when used under the proposed conditions of use (see Section 3.2.2).

1.2. Additional information

Coriander oil (CAS 8008-52-4, CoE154) from *Coriandrum sativum* L. 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. sativum* preparation when used to provide flavour in food. However, according to Regulation (EC) No 1334/2008[6] 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 dill seed extract, celery seed extract (oleoresin), caraway oleoresin/extract, and opoponax oil.

[4] On 2 April 2020, EFSA was informed by the applicant about the withdrawal of the applications on parsley oil, hares ear tincture, taiga root extract (sb), ajowan oil.

[5] On 9 December 2020, the applicant informed EFSA about the withdrawal of the application on celery tincture.

[6] 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'.

'Coriander oil' (Coriandri aetheroleum) is described in a monograph of the European Pharmacopoeia 11.1 (PhEur, 2023). It is defined as the essential oil obtained by steam distillation from the fruits of *C. sativum* L.

Many of the individual components of the essential oils under assessment have been already evaluated 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) and the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). The list of flavouring compounds currently authorised for food[7] and feed[8] uses together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000[9] and the corresponding EFSA opinion are given 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 (year)

CG	Chemical group	Product (EU register name)	FLAVIS No	EFSA opinion,* Year
01	Straight-chain primary aliphatic alcohols/ aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes	Decan-1ol	02.024	2013
		Decanal	05.010	
		Octyl acetate	09.007	
03	α,ß-Unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters with esters containing α,β-unsaturated alcohol and acetal containing α, β-unsaturated alcohols or aldehydes	Geraniol	02.012	2016a
		(Z)-Nerol	02.058	
		Dodec-2(*trans*)-enal	05.144	
		Neral	05.170	
		(E)-tetradec-2-enal	05.179	
		trans-3,7-Dimethylocta-2,6-dienal (geranial)	05.188	
		Geranyl acetate	09.011	
		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
		Citronellal	05.021	
05	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols	6-Methyhept-5-en-2-one	07.015	2015a, 2021a
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool	02.013	2012a, 2020
		α-Terpineol	02.014	2012a
		4-Terpinenol	02.072	
07	Primary alicyclic saturated and unsaturated alcohols/aldehydes/acids/acetals/esters with esters containing alicyclic alcohols	Myrtenyl acetate[(a)]	09.302	2017, CEF

[7] 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.

[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 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 opinion,* Year
08	Secondary alicyclic saturated and unsaturated alcohols, ketones, ketals and esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols	*d,l*-Borneol	02.016	2016c
		d,l-Bornyl acetate	09.017	
		d-Camphor[(b)]	07.215	2016c, 2023
		Pin-2-en-4-one[(a)]	07.196	2012, CEF
13	Furanones and tetrahydrofurfuryl derivatives	Linalool oxide	13.140	2012b
16	Aliphatic and alicyclic ethers	1,8-Cineole	03.001	2012c, 2021b
23	Benzyl alcohols, aldehydes, acids, esters and acetals	Benzaldehyde	05.013	2012d
		Methyl benzoate	09.725	
		Methyl salicylate	09.749	
31	Aliphatic and aromatic hydrocarbons and acetals containing saturated aldehydes	1-Isopropyl-4-methylbenzene (p-cymene)	01.002	2015b
		Terpinolene	01.005	
		α-Phellandrene	01.006	
		α-Terpinene	01.019	
		γ-Terpinene	01.020	
		d-Limonene	01.045	
		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	
		β-Ocimene	01.018	
		δ-3-Carene	01.029	
		β-Phellandrene[(a),(c)]	01.055	2011, CEF
		1,1,7-trimethyltricyclo [2.2.1.0.(2.6)]heptane[(a),(c)]	01.060	
		4(10)-Thujene (Sabinene)[(a)]	01.059	2015a, CEF
32	Epoxides	β-Caryophyllene oxide[(a)]	16.043	2014, CEF

(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): Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers not given. JECFA and EFSA evaluated the enantiomer *d*-camphor [07.159] (name in the register (1R,4R)-1,7,7-trimethylbicyclo[2.2.1] heptan-2-one) for use in food (EFSA, 2008 and in feed (EFSA FEDAP Panel, 2016c).
(c): 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).
*: FEEDAP opinion unless otherwise indicated.

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[10] in support of the authorisation request for the use of coriander oil from the fruit of *C. sativum* as a feed additive. The dossier was received on 7/9/2023 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00586.[11]

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.

[10] FEED dossier reference: FAD-2010-0221.
[11] The original application EFSA-Q-2010-01286 was split on 7/9/2023 and a new EFSA-Q-2023-00586 was generated.

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 2.[12]

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 additives. The evaluation report is related to the methods of analysis for each feed additive included in BDG 02 (Apiales and Austrobaileyales). During the assessment, the EURL issued a partial report[13] and an addendum of the report.[14] In particular, the EURL recommended a method based on gas chromatography coupled with flame ionisation detection (GC-FID) for the determination of the phytochemical marker linalool in *coriander oil*.[15]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of coriander oil from *C. sativum* 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 reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements (EFSA, 2012), Guidance for the preparation of dossiers for sensory additives (EFSA FEEDAP Panel, 2012e), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012f), 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 efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), 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, coriander oil, is an essential oil obtained by steam distillation from the fruit of *C. sativum* L. It is intended for use as a sensory additive (functional group: flavouring compounds) in feed and in water for drinking for all animal species.

3.1. Origin and extraction

C. sativum L. is an annual herb belonging to the family Apiaceae. It is native to the Mediterranean region but cultivated worldwide as a culinary herb. It is also said to have medicinal properties. All parts of the plant are used for culinary purposes. The aerial parts of the herb are referred to as cilantro or Chinese parsley while the term coriander is restricted to the dried fruit (commonly described as coriander seed).

The essential oil is extracted from the crushed mature fruit by steam distillation and then separated from the aqueous phase by decantation.

[12] Technical dossier/Supplementary information/Letter dated 29/4/2021.

[13] Preparations included in the partial report: dill herb oil, dill tincture, dong quai tincture, cumin oil, fennel tincture, parsley tincture, anise tincture, star anise tincture and ferula assa-foetida oil.

[14] Preparations included in the addendum: celery seed oil, caraway seed oil, coriander oil, taiga root tincture, fennel oil, common ivy extract (sb), ginseng tincture, anise oil, anise star oil, anise star terpenes and omicha tincture.

[15] The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0221_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.

3.2. Characterisation

3.2.1. Characterisation of the additive

Coriander oil is a colourless to pale yellow clear mobile liquid, with a characteristic and spicy odour. In five batches of the additive, the refractive index ranges (20°C) between 1.4634 and 1.4639 (specification: 1.462–1.470), the density (20°C) between 0.869 and 0.871 kg/L (specification: 0.862–0.878), the optical rotation between +10.12° and +11.16° (specification: +7° to +13°).[17] Coriander oil is identified with the single Chemical Abstracts Service (CAS) number 8008-52-4, the European Inventory of Existing Chemical Substances (EINECS) number 283-880-0, Flavor Extract Manufacturers Association (FEMA) 2334 and Council of Europe (CoE) 154.

For coriander oil, the product specifications used by the applicant are based on those developed by the International Organisation for Standardization (ISO) 3516:1997(E) for the oil of coriander fruit (*C. sativum* L.),[18] which were adapted to reflect the concentrations of the main volatile components of the essential oil. Nine constituents contribute to the specifications as shown in Table 2, with linalool selected as the phytochemical marker. Analysis of five batches of the additive showed compliance with these specifications when analysed by GC-FID and expressed as % of the total gas chromatographic peak area (% GC area).[19]

Table 2: Major constituents of the essential oil from the fruit of *Coriandrum sativum* L. as defined by specification: batch to batch variation based on the analysis of five batches by gas chromatography with flame ionisation detector (GC-FID). 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	Mean	Range
Linalool	78-70-6	02.013	65–78	71.7	67.3–76.4
α-Pinene	80-56-8	01.004	3–8.5	6.23	4.93–7.06
γ-Terpinene	99-85-4	01.020	2–7	4.41	3.48–5.07
Camphor[(a)]	76-22-2	–	3–6	4.59	3.84–5.39
Geranyl acetate	105-87-3	09.011	0.5–4.5	2.70	1.33–3.92
d-Limonene	138-86-3	01.045	0.5–5	2.67	1.19–3.69
Geraniol	106-24-1	02.012	0.1–3	1.41	0.72–2.20
Myrcene	123-35-3	01.008	0.1–2	1.05	0.90–1.19
α-Terpineol	98-55-5	02.014	≤ 1.5	0.32	0.18–0.57

EU: European Union; CAS no: Chemical Abstracts Service number; FLAVIS number: EU Flavour Information System numbers.
(a): Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers not given.

The applicant provided the full characterisation of the volatile constituents in five batches obtained by gas chromatography coupled with mass spectrometry (GC–MS).[20] In total, up to 52 constituents were identified and accounted on average for 99.3% (99.1–99.6%) of the % GC area. The nine constituents indicated in the product specifications accounted for about 92.1% on average (range 90.7–93.0%) of the % GC area. Besides the nine compounds, 14 other compounds were detected at individual levels > 0.1% and are listed in Table 3. These 23 compounds > 0.1% together, account on average for 98.5% (98.1–98.9%) of the GC area. The remaining 29 compounds (ranging between 0.001% and 0.1%) and accounting for 0.82% are listed in the footnote.[21] Based on the available data on the characterisation, coriander oil is considered a fully defined mixture (EFSA SC, 2019a).

17 Technical dossier/Supplementary information November 2020/Annex_II_ SIn_Reply_coriander_oil_CoA_chromatogram.
18 Technical dossier/Supplementary information November 2020/Annex_III_SIn_reply_coriander_oil_ISO.
19 Technical dossier/Supplementary information November 2020. GC-FID analysis/Table 3.
20 Technical dossier/Supplementary information November 2020/Annex_II_ SIn_Reply_coriander_oil _CoA_chromatogram.
21 Additional constituents: constituents (n = 9) between <0.1 and ≥0.05%: *trans*-3,7-dimethylocta-2,6-dienal (geranial), α-thujene, decan-1-ol, citronellol, citronellal, dodec-2(*trans*)-enal, *trans*-3,7-dimethyl-1,3,6-octatriene (*trans*-β-ocimene), decanal, 1,1,7-trimethyltricyclo[2.2.1.0.(2.6)]heptane, constituents (n = 20) between <0.05 and > 0.01%: neryl acetate, *cis*-linalool oxide (pyranoid), neral, pin-2-en-4-one, octyl acetate, α-phellandrene, *trans*-linalool oxide (pyranoid), nerol, *(E)*-tetradec-2-enal, 6-methylhept-5-en-2-one, δ-3-carene, 1,8-para-menthadien-4-ol, bornyl acetate, pinocarvone, methyl benzoate, sedanolide, β-caryophyllene epoxide, methyl salicylate, pseudolimonene and benzaldehyde.

Table 3: Constituents of the essential oil from the fruit of *Coriandrum sativum* L. accounting for > 0.1% of the % GC area (based on the analysis of five batches by gas chromatography–mass spectrometry). 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	% GC area Range
Linalool	78-70-6	02.013	58.72	56.2–60.5
α-Pinene	80-56-8	01.004	7.58	6.8–8.07
γ-Terpinene	99-85-4	01.020	6.56	6.02–6.94
Camphor	76-22-2	–	6.47	6.19–7.1
Geranyl acetate	105-87-3	09.011	5.56	4.89–6.1
d-Limonene	138-86-3	01.045	3.30	3.05–3.5
Geraniol	106-24-1	02.012	2.22	1.84–2.55
Myrcene	123-35-3	01.008	1.22	1.16–1.26
α-Terpineol	98-55-5	02.014	0.48	0.44–0.52
p-Cymene (1-isopropyl-4-methylbenzene)	99-87-6	01.002	1.75	1.18–2.50
Camphene	79-92-5	01.009	1.36	1.06–1.63
Terpinolene	586-62-9	01.005	0.92	0.87–0.97
β-Pinene (pin-2(10)-ene)	127-91-3	01.003	0.65	0.57–0.71
Sabinene (4(10)-thujene)	3387-41-5	01.059	0.28	0.20–0.38
Borneol	507-70-0	02.016	0.27	0.24–0.31
cis-Linalool oxide[(a)]	5989-33-3	–	0.25	0.14–0.34
4-Terpinenol	562-74-3	02.072	0.18	0.16–0.20
Myrtenyl acetate	1079-01-2	09.302	0.18	0.12–0.23
β-Phellandrene	555-10-2	01.055	0.16	0.14–0.20
β-Caryophyllene	87-44-5	01.007	0.10	0.08–0.14
1,8-Cineole	470-82-6	03.001	0.10	0.06–0.12
α-Terpinene	99-86-5	01.019	0.10	0.07–0.11
trans-Linalool oxide[(b)]	11063-78-8	–	0.10	0.04–0.15
Total			98.49	98.05–98.93[(c)]

EU: European Union; CAS no: Chemical Abstracts Service number; FLAVIS number: EU Flavour Information System numbers.
(a): Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers not given.
(b): Furanoid structure (5-ring), linalool oxide (*cis* and *trans*) identified with FLAVIS number [13.140].
(c): The values given for the Total (range) are the lowest and the highest values of the sum of the components in the five batches analysed.

3.2.1.1. Substances of concern

The applicant performed a literature search for information on the chemical composition of *C. sativum* and its preparations and the presence of compounds of known concern.[22] The presence of camphor (up to 6%) in the essential oil from the aerial parts of plants has been reported in the EFSA Compendium of botanicals (EFSA, 2012).[23] No other substances of concern were reported in the European Pharmacopoeia (PhEur, 2023) and the related commentary (commentary to the PhEur, 2019).

3.2.1.2. Impurities

The applicant referred to the 'periodic testing' of some representative flavourings premixtures for mercury, cadmium, lead, arsenic, fluoride, dioxins and polychlorinated biphenyls (PCBs), organo-chloride pesticides, organo-phosphorous pesticides, aflatoxins (B1, B2, G1, G2) and ochratoxin A. However, no data have been provided. Since coriander 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.

22 Technical dossier/Supplementary information November 2020/Literature_search_coriander_oi
23 Online version: https://www.efsa.europa.eu/en/data-report/compendium-botanicals

3.2.2. Shelf-life

The typical shelf-life of coriander 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).[24] However, no data supporting this statement were provided.

3.2.3. Conditions of use

Coriander oil is intended to be added to feed for all animal species without withdrawal. The maximum proposed use level in complete feed is 30 mg/kg for all animal species. Coriander oil is also intended for use in water for drinking for ruminants, horses and dogs at 5 mg/kg, and for veal calves at 10 mg/kg.

3.3. Safety

The safety assessment of coriander oil is based on the maximum use levels proposed by the applicant in complete feed.

Many of the components of coriander oil, accounting for about 92% of the total GC peak areas, have been previously assessed and considered safe for use as flavourings, and are currently authorised for use in food[7] without limitations and for use in feed[8] at individual use levels higher than those resulting from the intended use of the essential oil under assessment in feed, with the exception of linalool for some species (EFSA FEEDAP Panel, 2012a).[25] The list of the compounds already evaluated by the EFSA Panels is given in Table 1 (see Section 1.2). Subsequently, linalool was considered safe at 30 mg/kg complete feed for all animal species based on the results of tolerance studies with a mixture of flavourings referred to as 'TuttiFrutti mixture' in chickens for fattening, piglets and cattle for fattening (EFSA FEEDAP Panel, 2020).

Camphor (as a mixture of isomers) has not been evaluated for use as a flavouring but is closely related to the flavouring compound *d*-camphor [07.215] already assessed in CG 8. *d*-Camphor [07.215] was evaluated based on the application of the threshold of toxicological concern (TTC) approach and considered safe at individual use levels of 0.5 mg/kg complete feed for cattle, salmonids and non-food producing animals, and 0.3 mg/kg complete feed for pigs and poultry (EFSA FEEDAP Panel, 2016c). Recently, *d*-camphor was assessed in tolerance studies with a mixture of flavourings referred to as 'Herbal mixture' in chickens for fattening, piglets, cattle for fattening and salmons. The tolerance studies showed that *d*-camphor was safe up to 5 mg/kg complete feed (EFSA FEEDAP Panel, 2023). The FEEDAP Panel considers that the conclusions reached for *d*-camphor can be extrapolated to the mixture of isomers of camphor by applying read-across.

Two compounds listed in Table 1, β-phellandrene [01.055] and 1,1,7-trimethyltricyclo [2.2.1.0.(2.6)] heptane [01.060] (tricyclene), were evaluated in FGE25.Rev2 (EFSA CEF Panel, 2011) by 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). For these compounds, for which a concern for genotoxicity was excluded, EFSA requested additional toxicity data (EFSA CEF Panel, 2011). In the absence of such data, the EFSA CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015a). As a result, these compounds are not authorised for use as flavours in food. For these compounds, in the absence of toxicity data, the FEEDAP Panel applies the 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, 2019c).

Eleven components of coriander oil accounting for $< 0.5\%$ of the % GC area have not been previously assessed for use as flavourings.[26] The FEEDAP Panel notes that camphor, *cis*- and *trans*-linalool oxide (pyranoid and furanoid structures), *trans*-β-ocimene and α-thujene are aliphatic mono- or sesquiterpenes structurally related to flavourings already assessed in CG 8 and CG 31 and a similar metabolic and toxicological profile is expected. These lipophilic compounds are expected to be rapidly

[24] Technical dossier/Section II.

[25] The FEEDAP Panel concluded that the 'high use level proposed by the applicant for linalool (25 mg/kg complete feed) is safe for salmonids, veal calves, cattle for fattening and pets (excluding cats) without a margin of safety, with the exception for dogs (SF = 1.4). The safe use level for pigs and dairy cows is 20, for piglets 12 and for poultry 10 mg/kg complete feed' (EFSA FEEDAP Panel, 2012c).

[26] camphor, *cis*- and *trans*-linalool oxide (pyranoid and furanoid structures), *trans*-β-ocimene, α-thujene 1,8-para-menthadien-4-ol, pinocarvone, sedanolide and pseudolimonene

absorbed from the gastro-intestinal tract, oxidised to polar oxygenated metabolites, conjugated and excreted (EFSA FEEDAP Panel, 2016c,d).

The genotoxic potential for pseudolimonene, 1,8-para-menthadien-4-ol, pinocarvone and sedanolide was predicted using the OECD quantitative structure–activity relationship (QSAR) Toolbox.[27] The genotoxic potential of pseudolimonene was predicted as negative since profiling revealed no structural alerts. For the other compounds structural alerts were due to the presence of (i) vinyl/allyl alcohol group for 1,8-para-menthadien-4-ol, (ii) allyl/vinyl ketones polarised ketones, alpha and beta unsaturated carbonyls for pinocarvone and (iii) four-five membered lactones, acetates, polarised alkene, esters and oxolane for sedanolide. In all cases, predictions of mutagenicity by the Ames test were made by 'read-across' analyses of data available for similar substances to the target compounds (i.e. analogues obtained by categorisation). Categories were defined using general mechanistic and endpoint profilers as well as empirical profilers. Subcategorisation was performed in order to exclude analogues less similar to the target compounds. Mutagenicity read-across-based predictions were found consistently negative for all categories of analogues. 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 toxicological data with the additive under assessment, 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. 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.

As the additive under assessment is a fully defined mixture (the identified components represent > 99% 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. Linalool and camphor, which were included in tolerance studies with mixtures of flavourings 'TuttiFrutti' and 'Herbal mixture' (EFSA FEEDAP Panel, 2020, 2023) are assessed separately.

Components other than linalool and camphor

Based on considerations related to structural and metabolic similarities, the components were allocated to 12 assessment groups, corresponding to the chemical groups (CGs) 1, 3, 4, 5, 6, 7, 8, 13, 16, 23, 31 and 32, as defined in Annex I of Regulation (EC) No 1565/2000. For CG 31 ('aliphatic and aromatic hydrocarbons'), sub-assessment groups as defined in Flavouring Group Evaluation 25 (FGE.25) and FGE.78 were established (EFSA CEF Panel, 2015a,b). The allocation of the components to the (sub-)assessment groups is shown in Table 4 and in the corresponding footnote.

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 (bw) are used to express exposure in terms of mg/kg bw per day. The intake levels of the individual components are calculated for chickens for fattening, the species with the highest ratio of feed intake/bw per day, are shown in Table 4.

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 group, toxicological data were available to derive no observed adverse effect level (NOAEL) values. Structural and metabolic similarity among the components in the assessment groups were evaluated to explore the application of read-across. If justified, extrapolation from a known NOAEL of components of an assessment group to the other components of the group with no available NOAEL was made. If sufficient evidence is available for the members of a (sub)assessment group, a (sub)assessment group NOAEL was derived.

Toxicological data of sub-chronic studies, from which NOAEL values could be derived, were available for several compounds in CG 1 (EFSA FEEDAP Panel, 2013), citral [05.020] in CG 3 (EFSA FEEDAP Panel, 2016a), citronellol [02.011] and citronellyl derivatives in CG 4 (EFSA FEEDAP Panel, 2016b), 6-

[27] Technical dossier/Supplementary information November 2020/Annex VII_SIn_reply_coriander_oil_QSAR.

methylhept-5-en-2-one [07.015] in CG 5 (EFSA FEEDAP Panel, 2021a), terpineol [02.230][28] and linalool [02.013] in CG 6 (EFSA FEEDAP Panel, 2012a), 1,8-cineole [03.001] in CG 16 (EFSA FEEDAP Panel, 2021b), methyl salicylate in CG 23 (EFSA FEEDAP Panel, 2012d), myrcene [01.008], limonene [01.045], p-cymene [01.002] and β-caryophyllene [01.007] in CG 31 (EFSA CEF Panel, 2015a,b; EFSA FEEDAP Panel, 2015b, 2016d) and β-caryophyllene oxide in CG 32 (EFSA CEF Panel, 2014). For benzaldehyde [05.013] in CG 23, the FEEDAP Panel concluded that the maximum proposed concentration of 25 mg/kg complete feed is safe (EFSA FEEDAP Panel, 2012d). In addition, for benzyl alcohol [02.010] the FAF Panel established an acceptable daily intake (ADI) of 4 mg/kg bw per day, based on a NOAEL of 400 mg/kg bw per day from a chronic study in rats (EFSA FAF Panel, 2019).

For CG 1, a group NOAEL of 120 mg/kg bw was derived from the toxicological data available and selected as reference point for CG 1 compounds in the current assessment. Read-across was applied using the NOAEL of 345 mg/kg bw per day for citral [05.020] to extrapolate to geranyl acetate [09.011], geraniol [02.012], geranial [05.188], dodec-2(*trans*)enal [05.188], nerol [02.058], *(E)*-tetradec-2-enal [05.179], neral [05.170] and neryl acetate [09.213], and neryl formate [09.212] in CG 3. Similarly, the NOAEL of 50 mg/kg bw per day for citronellol [02.011] was applied to citronellal [05.021] in CG 4.

Considering the structural and metabolic similarities, the NOAEL of 250 mg/kg bw per day available for terpineol [02.230] and d-limonene [01.045] was selected as the reference point for the subgroup of terpinyl derivatives in CG 6, i.e. α-terpineol [02.014] and 4-terpinenol [02.072].

For benzaldehyde [05.013] in CG 23, read-across was applied from benzyl alcohol [02.010] applying to the NOAEL of 400 mg/kg bw per day an additional uncertainty factor of 2 to consider the higher reactivity of aldehyde compared to the alcohol.

The NOAELs of 44, 250, 154 and 222 mg/kg bw per day for the representative compounds of CG 31, myrcene [01.008], limonene [01.045], p-cymene [01.002] and β-caryophyllene [01.007] were applied, respectively, using read-across, to the compounds within sub-assessment groups II (*trans*-β-ocimene), III (γ-terpinene [01.020], terpinolene [01.005], α-terpinene [01.019], α-phellandrene [01.006]) and V (α-pinene [01.004], camphene [01.009], β-pinene [01.003], sabinene [01.059] and δ-3-carene [01.029])[29] (EFSA CEF Panel, 2015a,b).

For the remaining compounds,[30] NOAEL values were not available and read-across was not possible. Therefore, the TTC approach was applied (EFSA FEEDAP Panel, 2017b).

As the 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 4.

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). A MOET > 100 allowed for interspecies- and intra-individual variability (as in the default 10×10 uncertainty factor). The compounds resulting individually in a 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 coriander oil for the target species is summarised in Table 4. The calculations were done for chickens for fattening, the species with the highest ratio of feed intake/bw and represent the worst-case scenario at the use level of 30 mg/kg, without considering the presence of linalool and camphor.

As shown in Table 4, the MOET calculated at the proposed use level (30 mg/kg complete feed) was ≥ 100 for all assessment groups, except CG 13.

[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] (or δ-terpineol). The specification for terpineol [02.230] covers α-, β-, γ and δ-terpineol. Composition of mixture: 55–75% α-terpineol, 16–23% γ-terpineol, 1–10% *cis*-β-terpineol, 1–13% *trans*-β-terpineol and 0–1% δ-terpineol (EFSA CEF Panel, 2015b).

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

[30] 6-Methylhept-5-en-2-one [07.015], borneol [02.016], pin-2-en-4-one [07.196], bornyl acetate [09.017], pinocarvone, sedanolide, *cis*-linalol oxide, *trans*-linalool oxide, β-phellandrene [01.055], 1,1,7-trimethyltricyclo [2.2.1.0.(2.6)]heptane [01.060], pseudolimonene, α-thujene

[31] Decanal and octyl acetate (CG 1); geranial, dodec-2(*trans*)-enal, nerol, *(E)*-tetradec-2-enal, neral and neryl acetate (CG 3); 6-methylhept-5-en-2-one (CG 5); methyl benzoate, methyl salicylate and benzaldehyde (CG 23); α-terpinene and α-phellandrene CG 31,III); β-caryophyllene and δ-3-carene (CG 31,V).

Table 4: Compositional data, intake values, reference points and margin of exposure (MOE) for the individual components of coriander oil classified according to assessment groups and combined margin of exposure (MOET) for each assessment group

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								
Decan-1-ol	02.024	0.10	0.029	0.0026	(I)	120	46,902	
MOET CG 01								26,522
CG 3								
Geranyl acetate	09.011	6.10	1.830	0.1643	(I)	345	2,100	
Geraniol	02.012	2.55	0.765	0.0604	(I)	345	5,024	
MOET CG 03								1,481
CG 4								
Citronellol	02.011	0.062	0.019	0.0017	(I)	**50**	29,944	
Citronellal	05.021	0.057	0.017	0.0015	(I)	50	32,571	
MOET CG 03								15,601
CG 6								
α-Terpineol	02.014	0.52	0.156	0.0140	(I)	**250**	17,886	
4-Terpinenol	02.072	0.20	0.060	0.0054	(I)	250	46,647	
1,8-para-Menthadien-4-ol	n.a.	0.02	0.007	0.0006	III	*0.15*	232	
MOET CG 6								228
CG 7								
Myrtenyl acetate	09.302	0.232	0.070	0.0062	I	*3*	480	
CG 8								
Borneol	02.016	0.31	0.094	0.0084	I	*3*	357	
Pin-2-en-4-one	07.196	0.04	0.012	0.0011	II	*0.91*	845	
Bornyl acetate	09.017	0.02	0.005	0.0005	I	*3*	6,552	
Pinocarvone	n.a.	0.01	0.004	0.0004	III	*0.15*	398	
MOET CG 8								150
CG 11								
Sedanolide	n.a.	0.02	0.006	0.0005	III	*0.15*	278	
CG 13								
cis-Linalool oxide (5-ring)	13.140	0.34	0.103	0.0092	II	*0.91*	99	
trans-Linalool oxide	13.140	0.15	0.046	0.0041	II	*0.91*	219	
cis-Linalool oxide (6-ring)	n.a.	0.05	0.015	0.0013	II	*0.91*	676	
trans-Linalool oxide	n.a.	0.03	0.008	0.0007	II	*0.91*	1,352	
MOET CG 13								59
CG 16								
1,8-Cineole	03.001	0.12	0.036	0.0033	(II)	**100**	30,687	

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 31, II (Acyclic alkanes)								
Myrcene	01.008	1.26	0.378	0.0339	(I)	**44**	1,297	
trans-β-Ocimene	n.a.	0.06	0.018	0.0016	(I)	44	27,691	
MOET CG 31, II								1,239
CG 31,III (Cyclohexene hydrocarbons)								
γ-Terpinene	01.020	6.94	2.082	0.1869	(I)	250	1,338	
Limonene	01.001	3.50	1.050	0.0943	(I)	**250**	2,652	
Terpinolene	01.005	0.97	0.290	0.0260	(I)	250	9,619	
β-Phellandrene	01.055	0.20	0.060	0.0054	I	*3*	560	
Pseudolimonene	n.a.	0.01	0.003	0.0003	I	*3*	11,139	
MOET CG 31,III								322
CG 31, IVe (Aromatic hydrocarbons)								
p-Cymene	01.002	2.50	0.750	0.0673	(I)	**154**	2,287	
CG 31,V (Bi-, tricyclic, non-aromatic hydrocarbons)								
α-Pinene	01.004	8.07	2.421	0.2173	(I)	222	1,021	
Camphene	01.009	1.63	0.489	0.0439	(I)	222	5,057	
β-Pinene	01.003	0.71	0.214	0.0192	(I)	222	11,577	
Sabinene	01.059	0.38	0.113	0.0102	(I)	222	21,865	
α-Thujene	n.a.	0.07	0.021	0.0019	I	*3*	1,569	
Tricyclene	01.060	0.05	0.014	0.0013	I	*3*	2,370	
MOET CG 31, V								419

(a): Intake calculations for the individual components are based on the use level of 30 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 (no observed adverse effect level (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.

From the lowest MOET of 59 for chickens for fattening, the MOET for CG 13 compounds was calculated for the other target species considering the respective daily feed intake and conditions of use. The results are summarised in Table 5.

Table 5: Combined margin of exposure (MOET) calculated for the different target animal categories at the proposed use level in feed

	Body weight (kg)	**Feed intake (g DM/day)**	**Proposed use level (mg/kg complete feed)**	**Lowest MOET CG 13**	**Maximum safe use level (mg/kg complete feed)**[(a)]
Chicken for fattening	2	158	30	59	18
Laying hen	2	106	30	88	26
Turkey for fattening	3	176	30	79	24
Piglet	20	880	30	106	30

	Body weight (kg)	Feed intake (g DM/day)	Proposed use level (mg/kg complete feed)	Lowest MOET CG 13	Maximum safe use level (mg/kg complete feed)[(a)]
Pig for fattening	60	2,200	30	126	30
Sow lactating	175	5,280	30	155	30
Veal calf (milk replacer)	100	1,890	30	265	30
Cattle for fattening	400	8,000	30	233	30
Dairy cow	650	20,000	30	150	30
Sheep/goat	60	1,200	30	233	30
Horse	400	8,000	30	233	30
Rabbit	2	100	30	93	28
Salmon	0.12	2.1	30	259	30
Dog	15	250	30	274	30
Cat[(2)]	3	60	30	233	14
Ornamental fish	0.012	0.54	30	932	30

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

Table 5 shows that for all species the MOET exceeds the value of 100, except for poultry species and rabbits. For these species, the maximum safe use levels in feed were calculated to ensure a 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 a low capacity for glucuronidation (Court and Greenblatt, 1997; Lautz et al., 2021), the use of coriander oil as additive in cat feed needs a wider MOE. A MOET of 500 is considered adequate. The resulting maximum safe levels in feed (without considering linalool and camphor) are shown in Table 5.

Linalool and camphor

The applicant included the two compounds, linalool and camphor, in tolerance studies with mixtures of flavourings ('TuttiFrutti mixture' and 'Herbal mixture') to demonstrate their safe use at higher levels than those currently evaluated as safe in feed (EFSA FEEDAP Panel, 2020, 2023).

For linalool [02.013] the applicant provided new evidence in the form of tolerance trials in chickens for fattening, piglets and cattle for fattening, which showed that linalool was safe up to 30 mg/kg complete feed for all animal species (EFSA FEEDAP Panel, 2020). Based on the proposed conditions of use of coriander oil (30 mg/kg complete feed), the level of linalool at the highest measured concentration (60.5%) and at the highest specification (78%) would be 18.2 mg/kg and 23.5 mg/kg, respectively, which are considered safe for all animal species.

Similarly, for *d*-camphor [07.215], the applicant provided new evidence in the form of tolerance trials in chickens for fattening, piglets, cattle for fattening and salmons, which showed that *d*-camphor was safe up to 5 mg/kg complete feed for all animal species (EFSA FEEDAP Panel, 2023). The FEEDAP Panel considers that the conclusions reached for *d*-camphor can be extrapolated to *l*-camphor by applying read-across. Therefore, based on the proposed conditions of use of 30 mg/kg complete feed, the level of camphor in feed from the use of coriander oil would be 1.8 mg/kg at the highest specification (6%)[32] and is considered safe for all animal species.

Use in water for drinking

Coriander oil is also intended for use in water for drinking at 10 mg/kg for veal calves (milk replacers), and at 5 mg/kg for ruminants, horses and dogs.

For veal calves, the use of the additive at 10 mg/kg water for drinking can be considered safe only when added to the water for drinking but not to the water used to prepare the milk replacer.

For ruminants and horses, safe concentrations of an additive cannot be consistently extrapolated from feed to water using a fixed ratio of feed to water intake. The proposed use concentration in water of 5 mg/kg is only six times lower than the maximum proposed concentration in feed. This factor of 6 would not be considered sufficient to guarantee that the exposure of the target species to

[32] A concentration of camphor (7.1%, see Table 3) higher than the proposed specification was analysed by GC–MS, a method which is not used to set specifications. In the same batches, the concentration of camphor analysis by GC-FID was 5.39% (Table 2), in compliance with the proposed specification.

the additive via water or via feed would be comparable. However, the Panel notes that the MOET associated to the maximum proposed concentration in feed for ruminants and horses was at least 150 (dairy cows). Considering this high MOE, the proposed use level in water for drinking of (5 mg/kg) is considered safe for ruminants and horses.

For dogs, safe concentrations of an additive cannot be consistently extrapolated from feed to water using a fixed ratio of feed to water intake. However, in a worst-case scenario of a high-water intake it seems likely that the amount of water drunk is less than six times the amount of feed consumed. Therefore, considering that the proposed use level in water for drinking for dogs, 5 mg/kg water, is six times lower than the maximum proposed concentration in feed, the use of the additive at the proposed use level in water for drinking is considered safe.

The FEEDAP Panel considers 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 for all animal species.

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 coriander oil are summarised in Table 6.

Table 6: Maximum safe concentrations of coriander oil in complete feed (mg/kg) for all animal species and categories

Animal categories	Maximum safe concentration (mg/kg complete 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	18
Laying hens and other laying/reproductive birds	26
Turkeys for fattening	24
Pigs for fattening	30
Piglets and other Suidae species for meat production or reared for reproduction	30
Sows and other Suidae species for reproduction	30
Veal calves (milk replacer)	30
Cattle for fattening, other ruminants[(b)] for fattening or reared for milk production/reproduction and camelids at the same physiological stage	30
Dairy cows and other ruminants[(b)] and camelids for milk production or reproduction	30
Horses and other Equidae	30
Rabbits	28
Salmonids and minor fin fish	30
Dogs	30
Cats	14
Ornamental fish	30
Any other species	14

(a): Complete feed containing 88% DM, milk replacer 94.5% DM.
(b): Including sheep/goat.

The proposed conditions of use for veal calves (10 mg/kg) and ruminants, horses and dogs (5 mg/kg) are considered safe provided that the use in water for drinking alone or in combination with the use in feed should not exceed the daily amount that is considered safe when consumed via feed alone for all animal species.

3.3.2. Safety for the consumer

Coriander oil obtained by steam distillation of the dried fully ripe coriander fruit is added to a wide range of food for flavouring purposes. Although individual consumption figures for the EU are not available, the Fenaroli's handbook of flavor ingredients (Burdock, 2009) cites intake values of 1.27 mg/kg bw per day for coriander fruit and 0.049 mg/kg bw per day for coriander oil.

The majority 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 feed (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 under assessment. However, the Panel recognises that the constituents of coriander oil are expected to be extensively metabolised and excreted in the target species.

The FEEDAP Panel considers that it is unlikely that consumption of products from animals given coriander oil in feed at the proposed maximum use level would significantly increase human background exposure. Thus, no safety concern would be expected for the consumer from the use of coriander oil up to the maximum proposed use level in feed.

3.3.3. Safety for the user

No specific data were provided by the applicant regarding the safety of the additive for users. However, there is limited evidence of dermal irritation and sensitisation potential from the literature (Burdock and Carabin, 2009).

The applicant also provided a safety data sheet[33] for coriander oil where hazards of skin and eye irritancy and sensitisation have been identified for users.

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

3.3.4. Safety for the environment

C. sativum is a species native to the Mediterranean and is cultivated worldwide as a culinary herb. Use of the essential oil under the proposed conditions of use in animal production is not expected to pose a risk to the environment.

3.4. Efficacy

Coriander fruit and coriander oil are listed in Fenaroli's Handbook of Flavor Ingredients (Burdock, 2009) and by FEMA with the reference number 2333 and 2334, respectively.

Since the fruit of *C. sativum* and its 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 for the essential oil under assessment.

4. Conclusions

Coriander oil from *C. sativum* L. may be produced from plants of different geographical origins and by various processes resulting in preparations with different composition and toxicological profiles. Therefore, the following conclusions apply only to coriander oil, which contains ≤ 6% camphor and is produced by steam distillation from the fruit of *C. sativum*.

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

Animal categories	Maximum safe concentration (mg/kg complete 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	18
Laying hens and other laying/reproductive birds	26
Turkeys for fattening	24
Pigs for fattening	30
Piglets and other Suidae species for meat production or reared for reproduction	30
Sows and other Suidae species for reproduction	30
Veal calves (milk replacer)	30

[33] Technical dossier/Supplementary Information November 2020/Annex_IX_SIn reply_coriander_oil_MSDS. Aspiration hazard (H304), skin irritant (H314), skin sensitiser (H317), eye irritant (H318).

Animal categories	Maximum safe concentration (mg/kg complete feed)[(a)]
Cattle for fattening, other ruminants[(b)] for fattening or reared for milk production/reproduction and camelids at the same physiological stage	30
Dairy cows and other ruminants[(b)] and camelids for milk production or reproduction	30
Horses and other Equidae	30
Rabbits	28
Salmonids and minor fin fish	30
Dogs	30
Cats	14
Ornamental fish	30
Any other species	14

(a): Complete feed containing 88% DM, milk replacer 94.5% DM
(b): Including sheep/goats.

The proposed conditions of use for veal calves (10 mg/kg) and ruminants, horses and dogs (5 mg/kg) are considered safe provided that the use in water for drinking alone or in combination with the 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 coriander oil up to maximum proposed use level in feed.

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

The use of coriander oil at the proposed use level in feed is not expected to pose a risk to the environment.

Since the fruit of *C. sativum* and its 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 for the essential oil under assessment.

5. Documentation provided to EFSA/Chronology

Date	Event
28/10/2010	Dossier received by EFSA. Botanically defined flavourings from Botanical Group 02 – Apiales and Austrobaileyales 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
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
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
27/02/2019	Partial withdrawal by applicant (EC was informed) for the following additives: dill seed extract, celery seed extract (oleoresin), caraway oleoresin/extract, and opoponax oil
24/06/2019	Application validated by EFSA – Start of the scientific assessment
03/07/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterization, safety for the target species, safety for the consumer, safety for the user, safety for the environment*
30/09/2019	Comments received from Member States
30/11/2020	Reception of supplementary information from the applicant (partial dataset on coriander oil) – Scientific assessment remains suspended
31/10/2022	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives – partial report related to nine additives (*dill herb oil, dill tincture, dong quai tincture, cumin oil, fennel tincture, parsley tincture, anise tincture, star anise tincture and ferula assa-foetida oil*)

Date	Event
16/12/2022	Reception of an addendum of the Evaluation report of the European Union Reference Laboratory for Feed Additives – final report related to 11 additives (*celery seed oil, caraway seed oil, coriander oil, taiga root tincture, fennel oil, common ivy extract (sb), ginseng tincture, anise oil, anise star oil, anise star terpenes and omicha tincture*)
07/09/2023	The application was split and a new EFSA-Q-2023-00586 was assigned to the preparation included in the present assessment
07/09/2023	Scientific assessment re-started
28/09/2023	Opinion adopted by the FEEDAP Panel on coriander oil (EFSA-Q-2023-00586). End of the Scientific assessment for the preparations included in the present assessment. The assessment of other preparations belonging to BDG 02 is still ongoing

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Abbreviations

AFC	EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
BDG	botanically defined group
BMD	benchmark dose
$BMDL_{10}$	benchmark dose (BMD) lower confidence limit for a benchmark response of 10%
bw	body weight
CAS	Chemical Abstracts Service
CD	Commission Decision
CDG	chemically defined group
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CG	Chemical Group
CoE	Council of Europe
DM	dry matter
EEIG	European economic interest grouping
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
FEMA	Flavor Extract Manufacturers Association
FFAC	Feed Flavourings authorisation Consortium of (FEFANA) the EU Association of Specialty Feed Ingredients and their Mixtures
FGE	Flavouring Group Evaluation
FLAVIS	The EU Flavour Information System
FL-No	FLAVIS number
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC–MS	gas chromatography–mass spectrometry
ISO	International Standard Organization
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
MOE	margin of exposure
MOET	combined margin of exposure (total)
NOAEL	no observed adverse effect level
QSAR	quantitative structure–activity relationship
SC	EFSA Scientific Committee
TTC	threshold of toxicological concern