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Safety and efficacy of an essential oil from *Elettaria cardamomum* (L.) Maton when used as a sensory additive in feed for all animal species

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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 an essential oil from the seeds of *Elettaria cardamomum* (L.) Maton when used as a sensory additive for all animal species. Characterisation of the essential oil identified 37 components accounting for > 99% of its composition, with terpineol acetate (> 35%) and 1,8-cineole (> 20%) being the most prevalent compounds. In the absence of toxicological data of the feed additive itself, a component-based approach was applied to assess the safety of the essential oil as a mixture. Based on structural and metabolic similarity, the components of cardamom oil were allocated to seven assessment groups. Assuming the absence of toxicologically relevant interactions among components, dose addition was applied within each assessment group by calculating the combined margin of exposure as a basis for risk characterisation. The FEEDAP Panel concluded that the additive under assessment is safe at the proposed use level of 5 mg/kg in feed for all animal species. A concentration of 5 mg/L water for drinking is considered safe for all animal species. The use of cardamom essential oil in animal feed is considered safe for the consumer. In the absence of studies, the Panel cannot conclude on the safety for the users when handling the additive. The use of the essential oil under assessment in animal production is not expected to pose a risk for the environment. Since the seeds of *E. cardamomum* and their preparations are recognised to flavour food and their function in feed would be essentially the same, no further demonstration of efficacy is considered necessary. The Panel made a recommendation to limit the content of methyleugenol in the oil.

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Keywords: sensory additives, flavourings compounds, essential oil, cardamom, *Elettaria cardamomum* (L.) Maton, safety, combined margin of exposure

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ 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 and in addition, Article 10(2) of that Regulation also 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 the Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)² for authorisation/re-evaluation of nine preparations (namely turmeric oil, oleoresin, extract (sb) and tincture from *Curcuma longa* L., cardamom oil from *Elettaria cardamomum* (L.) Maton, ginger oil, oleoresin, tincture and extract from *Zingiber officinale* Roscoe) belonging to botanically defined group (BDG) 9 – Zingiberales, when used as feed additives for all animal species (category: sensory additives; functional group: flavourings). During the course of the assessment, this application was split and the present opinion concerns only cardamom essential oil (*Elettaria cardamomum* (L.) Maton) for all animal species.

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 2011.³

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 cardamom essential oil (*E. cardamomum* (L.) Maton), when used under the proposed conditions of use (see Section 3.2.3).

The remaining eight preparations belonging to BDG 9 – Zingiberales under application will be assessed in separate opinions.

1.2. Additional information

Cardamom oil from *E. cardamomum* (L.) Maton 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 *E. cardamomum* (L.) Maton preparation when used to provide flavour in food. However, according to Regulation (EC) No 1334/2008⁴ flavouring preparations produced from food, may be used without an evaluation and approval as long as 'they do not, on the basis of the scientific evidence available, pose a safety risk to the health of the consumer, and their use does not mislead the consumer'.

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on 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 26 February 2013, EFSA duly 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. On 24 July 2017, EFSA informed the applicant that the evaluation process restarted.

⁴ 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.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of an essential oil from *E. cardamomum* (L.) Maton as a feed additive.

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has sought to use 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 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. The applicant submitted a written agreement to use the data submitted for the assessment of chemically defined flavourings (dossiers, publications and unpublished reports) for the risk assessment of cardamom oil.⁶

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of flavourings of cardamom essential oil in animal feed. The Executive Summary of the EURL report can be found in Annex A.⁷

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of cardamom essential oil (*E. cardamomum* (L.) Maton) is in line with the principles laid down in Regulation (EC) No 429/2008⁸ 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, 2012), Guidance for the preparation of dossiers for sensory additives (EFSA FEEDAP Panel, 2012a), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), Guidance on the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017b) and Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA SC, 2019).

3. Assessment

The additive under assessment is an essential oil from *E. cardamomum* (L.) Maton and is intended for use as a sensory additive (flavouring) in feed and in water for drinking.

3.1. Origin and extraction

The common name 'cardamom' describes the seeds of a number of plant species all belonging to the Zingiberaceae family and is also used as vernacular name to describe the plants themselves. The true cardamom is taken to apply to *E. cardamomum* (L.) Maton, also called the green cardamom or the small cardamom in reference to the physical appearance of the seeds. The name cardamom is also applied to another species of the same genus *E. ensal* (Sri Lankan wild cardamom) which is morphologically similar to *E. cardamomum* but produces a seed with very different chemical characteristics. In addition to *Elettaria* spp., cardamom is also used to describe *Amomum subulatum*, whose seeds are larger than those from *E. cardamomum* (L.) Maton and darker in colour. Seeds from this species are often referred to as Nepal cardamom or black cardamom. Seeds from *Aframomum corrorima*, a plant of limited cultivation found in some African countries also may be described as Korarima cardamom, but more usually as 'grains of paradise'. The different types of cardamom seeds have a long traditional use as a spice to flavour food.

⁵ FEED dossier reference: FAD-2010-0335.

⁶ Technical dossier/Supplementary information February 2018/2018-01-30_SInReply_cardamom.

⁷ The full report is available on the EURL website <https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2010-0335.pdf>

⁸ 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.

E. cardamomum (L.) Maton is native to southern India but has been subsequently introduced as a commodity crop in many areas of the tropics. In particular, it was introduced in the early part of the 1900s into Guatemala, now the largest producer followed by India. In addition, Sri Lanka, Papua New Guinea and Tanzania are significant producers and exporters.

The essential oil is extracted by steam distillation from the crushed seeds harvested before maturity. The use of other extraction methods such as cold pressing (Bernhard et al., 1971), ultrasound assisted extraction (Sereshti et al., 2012), ultrasound–hydrodistillation (Morsy, 2015) has been reported. Supercritical fluid extraction with CO₂ (Marongiu et al., 2004) is used to limited extent.

The amount of oil present in the freshly harvested seeds generally is around 5% and may reach 8% by weight under some conditions. However, the concentration of oil decreases on storage and whole seeds imported for later extraction give lower yields (Leela et al., 2008).

3.2. Characterisation

3.2.1. Characterisation of the essential oil

This application concerns the essential oil derived by steam distillation from the seeds of *E. cardamomum* (L.) Maton. The product is a colourless to pale yellow liquid with spicy (cineolic) odour. In five batches of the additive, the optical rotation ranged between 22.3 and 27.2 (specification: 22.0–44.0), the refractive index between 1.4628 and 1.4634 (specification: 1.4620–1.4660), and density (20°C) between 0.925 and 0.930 g/mL (specification: 0.917–0.947).⁹ Cardamom essential oil is identified with the single Chemical Abstracts Service (CAS) number 8000-66-6, European Inventory of Existing Chemical Substances (EINECS) number 288-922-1 and Flavor Extract Manufacturers Association (FEMA) number 2241.

The product specifications are based on the standards developed by the International Organisation for Standardization (ISO) 4733:2004 for Oil of Cardamom (*E. cardamomum* (L.) Maton)), which reflect the concentrations of the main components of the essential oil, namely 1,8-cineole, terpineol acetate, linalyl acetate, linalool, limonene, sabinene, terpinen-4-ol, α -terpineol, α -pinene, myrcene and *trans*-nerolidol. Analysis of five batches of the additive⁹ showed compliance with these specifications (Table 1). These 11 compounds account for about 88.1% of the product, expressed as area % of the gas chromatographic (GC) profile.

Table 1: Major constituents of the essential oil from *Elettaria cardamomum* (L.) Maton as defined by the ISO standard: specifications and batch to batch variation based on the analysis of five batches. The content of each constituent is expressed as the percentage of the area 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	Specification GC Area %	Percentage of oil	
					Mean ^(a)	Range
Terpineol acetate ^(b)		8007-35-0	09.830	30–42	35.05	33.75–37.30
1,8-Cineole		470-82-6	03.001	16–35	23.31	20.44–24.13
Linalyl acetate		115-95-7	09.013	5–9	6.95	6.83–7.01
4(10)-Thujene (sabinene)		3387-41-5	01.059	2–6	4.21	2.99–4.78
Limonene		5989-27-5	01.045	1–6	4.39	4.29–4.70
Linalool		78-70-6	02.013	2–6	4.17	3.88–4.62
Pin-2(3)-ene (α -pinene)		80-56-8	01.004	1–3	2.50	1.93–2.76
Myrcene		123-35-3	01.008	1–4	2.28	1.78–2.63
α -Terpineol		98-55-5	02.014	1–3	2.18	1.88–2.35
Terpinen-4-ol		562-74-3	02.072	0.5–2.5	1.44	1.23–2.03
<i>trans</i> -Nerolidol		7212-44-4	02.018	0.5–2	1.48	1.20–1.56
Total					88.11	

⁹ Technical dossier/Supplementary information February 2018/Annex_II_SIn_reply_Cardamom_oil_Specification_conf.

CAS no. Chemical Abstracts Service number; FLAVIS number: EU Flavour Information System numbers.

(a): Mean calculated on five batches.

(b): CAS number in the Register refers to α -terpinyl acetate (Regulation (EC) No 1334/2008).¹⁰

The applicant provided the full characterisation of the same five batches [REDACTED] which accounted for 99.43% (99.15–100%) of the product. Besides the 11 compounds indicated in the product specifications, 27 other compounds have been identified and quantified in the five batches and accounted on average for 11.32% (10.42–13.88%) of the product. They are listed in Table 2.

Table 2: Constituents of the essential oil from *Elettaria cardamomum* (L.) Maton not included in the ISO standard (based on the analysis of five batches). The content of each constituent is expressed as the percentage of the area of the corresponding chromatographic peak (% GC area). The major components are described in Table 1

Constituent EU register name	CAS No	FLAVIS No	Percentage of oil	
			Mean ^(a)	Range
<i>trans</i> -Sabinene hydrate ^(b)	546-79-2	02.085	[REDACTED]	[REDACTED]
Geraniol	106-24-1	02.012	[REDACTED]	[REDACTED]
Geranyl acetate ^(c)	105-87-3	09.011	[REDACTED]	[REDACTED]
1-Isopropyl-4-methylbenzene (<i>p</i> -cymene)	99-87-6	01.002	[REDACTED]	[REDACTED]
β -Bisabolene	495-61-64	01.028	[REDACTED]	[REDACTED]
β -Terpineol	138-87-4	02.097	[REDACTED]	[REDACTED]
Pin-2(10)-ene (β -pinene)	127-91-3	01.003	[REDACTED]	[REDACTED]
α -Zingiberene	495-60-3	–	[REDACTED]	[REDACTED]
Citronellol ^(d)	106-22-9	02.011	[REDACTED]	[REDACTED]
Dihydroterpinyl acetate	80-25-1	–	[REDACTED]	[REDACTED]
Geranial	141-27-5	05.188	[REDACTED]	[REDACTED]
Bornyl acetate	76-49-3	09.017	[REDACTED]	[REDACTED]
Decanoic acid	334-48-5	08.011	[REDACTED]	[REDACTED]
γ -Terpinene	99-85-4	01.020	[REDACTED]	[REDACTED]
Fenchyl alcohol ^(*)	1632-73-1	02.038	[REDACTED]	[REDACTED]
β -Sesquiphellandrene	20307-83-9	–	[REDACTED]	[REDACTED]
α -Selinene	473-13-2	–	[REDACTED]	[REDACTED]
Nerol	106-25-2	02.058	[REDACTED]	[REDACTED]
α -Terpinene ^(e)	99-86-5	01.019	[REDACTED]	[REDACTED]
Octyl acetate	112-14-1	09.007	[REDACTED]	[REDACTED]
Terpinolene	586-62-9	01.005	[REDACTED]	[REDACTED]
Camphene	79-92-5	01.009	[REDACTED]	[REDACTED]
Geranic acid	4698-08-2	–	[REDACTED]	[REDACTED]
β -Caryophyllene	87-44-5	01.007	[REDACTED]	[REDACTED]
β -Germacrene	15423-57-1	–	[REDACTED]	[REDACTED]
Farnesol	4602-84-0	02.029	[REDACTED]	[REDACTED]
δ -Germacrene	23986-74-5	01.042	[REDACTED]	[REDACTED]
Total			[REDACTED]	[REDACTED]

CAS no. Chemical Abstracts Service number; FLAVIS number: EU Flavour Information System numbers.

(a): Mean calculated on five batches unless a different number of batches is indicated into parenthesis.

(b)–(e): The following chromatographic peaks showed incomplete GC resolution: (b) *trans*-sabinene hydrate + δ -elemene; (c) geranyl acetate + δ -cadinene; (d) citronellol + aryl curcumene; (e) α -terpinene + 1,4-cineole.

(*): Three possible compounds were attributed to the same GC peak detected in one batch of the essential oil: fenchyl alcohol, isobornyl acetate or β -elemene at 0.38%.

¹⁰ 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 food and amending Council Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34.

The applicant performed a literature search regarding substances of concern and chemical composition of the plant species *E. cardamomum* (L.) Maton and its preparations.¹² Methyleugenol is a natural constituent of essential oils of a number of plants widely used in foodstuffs as flavouring agents, which has been recognised as a genotoxic carcinogen. The occurrence of methyleugenol has been reported at around 0.1% in cardamom oil from *E. cardamomum* (L.) Maton (EMEA, 2005). The content of methyleugenol in the five batches of the additive under assessment was below the limit of detection (LOD, < 0.0002%). Although the batches of the essential oil under assessment do not contain detectable amounts of methyleugenol, uncertainty remains on the presence of this compound in oils meeting the same description.

3.2.2. Impurities

No information on the concentrations of undesirable compounds in the essential oil is given. The applicant makes reference to the 'periodic testing' of some representative flavourings premixtures for heavy metals (mercury, cadmium and lead), arsenic, fluoride, dioxins and dioxin-like polychlorinated biphenyls (PCBs), organochloride pesticides, organophosphorous pesticides, aflatoxin B1, B2, G1, G2 and ochratoxin A. However, the relevance to the oil under application is unclear. Since cardamom oil is produced by steam distillation, the likelihood of any measurable carry-over of heavy metals is low except for mercury (Tascone et al., 2014).

3.2.3. Shelf-life

The typical shelf-life of pure flavouring compounds is stated to be at least 12 months, when stored in tightly closed containers under standard conditions. No separate or additional stability studies were provided for the essential oil under application.

3.2.4. Conditions of use

Cardamom essential oil is intended to be added to feed or water for drinking for all animal species without withdrawal. The proposed use level is 5 mg/kg complete feed.¹³ No use level has been proposed by the applicant for the use in water for drinking.

3.3. Safety

The assessment of safety is based on the use level proposed by the applicant (5 mg/kg complete feed).

3.3.1. Safety for the target species

Tolerance studies and/or toxicological studies 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. 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, 2019).

As the additive under assessment is sufficiently characterised (up to 99.4% on average), the FEEDAP Panel applied a component-based approach to assess the safety for target species of the essential oil from the seeds of *E. cardamomum* (L.) Maton.

Based on considerations related to structural and metabolic similarities, the components were allocated to seven assessment groups, corresponding to the chemical groups (CGs) 6, 16, 31, 3, 4, 8 and 1, as defined in Annex I of Regulation (EC) No 1565/2000.¹⁴ For chemical group 31 ('aliphatic and aromatic hydrocarbons'), the application of subassessment groups as defined in Flavouring Group

¹² Technical dossier/Supplementary Information February 2018/Annex_IV.

¹³ Technical dossier/Supplementary Information February 2018. The proposed use level of 25 mg/kg was reduced during the course of the assessment to 5 mg/kg.

¹⁴ 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.

Evaluation 25 (FGE.25) and FGE.78 is applied (EFSA CEF Panel, 2015a,b). The allocation of the components to the (sub-)assessment groups is shown in Table 3.

For each component in the assessment group, exposure in 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, 2017a). Default values on body weight are used to express exposure in terms of mg/kg body weight (bw). The intake levels of the individual components calculated for chickens for fattening, the species with the highest ratio of feed intake/body weight, are shown in Table 3.

For hazard characterisation, each component of an assessment group was first assigned to the structural class according to Cramer classification. 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 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 for subchronic studies, from which NOAEL values could be derived, were available for terpineol [02.230] and linalool [02.013] in CG 6 (EFSA FEEDAP Panel, 2012d), 1,8-cineole [03.001] in CG 16 (EFSA FEEDAP Panel, 2012c), limonene [01.045], *p*-cymene [01.002], myrcene [01.008] and β -caryophyllene [01.007] in CG 31 (EFSA FEEDAP Panel, 2015, 2016c), geraniol [02.012] and farnesol [02.029] in CG 3 (EFSA FEEDAP Panel, 2016a), citronellol [02.011] in CG 4 (EFSA FEEDAP Panel, 2016b), and octyl acetate [09.007] and decanoic acid [08.011] in CG 1 (EFSA FEEDAP Panel, 2013).¹⁵

Considering the structural and metabolic similarities in CG 6, read-across was applied using the NOAEL of 250 mg/kg bw per day for terpineol [02.230] to extrapolate to α -terpineol [02.014], β -terpineol [02.097], terpinen-4-ol [02.072] terpineol acetate [09.830] and dihydroterpinyl acetate, and the NOAEL of 117 mg/kg bw per day for linalool [02.013] to extrapolate to linalyl acetate [09.013] and nerolidol [02.018].

In CG 31, the NOAELs for the representative compounds limonene [01.045] and β -caryophyllene [01.007] were applied, respectively, using read-across to the compounds within sub-assessment groups III (γ -terpinene [01.020], α -terpinene [01.019], terpinolene [01.005], β -bisabolene [01.028] and β -sesquiphellandrene) and group V (β -pinene [01.003], α -pinene [01.004], camphene [01.009], sabinene [01.059] and α -selinene [01.059]) (EFSA CEF Panel, 2015a,b). The FEEDAP Panel applied the same NOAEL value from sabinene [01.059] to *trans*-sabinene hydrate [02.085] in CG 8.

Read-across was also applied using the NOAEL of 345 mg/kg bw per day for geraniol [02.012] to geranial [05.188], geranic acid [08.081], geranyl acetate [09.011] and *Z*-nerol [02.058] and selected as the reference point for CG 3.

For the remaining compounds, namely α -zingiberene, β -elemene, δ -germacrene [01.042], β -germacrene, fenchyl alcohol [02.038] and Δ^1 -bornyl acetate [09.017], toxicity studies and NOAEL values performed with the compounds under assessment were not available and read-across was not possible. Therefore, the threshold of toxicological concern (TTC) approach was applied (EFSA FEEDAP Panel, 2012a, 2017a). All these compounds belong to Cramer class I.

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 mg/kg bw per day for Cramer Class I compounds). Reference points selected for each compound are shown in Table 3.

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 PPR Panel, 2008; EFSA, 2013a; EFSA SC, 2019). A MOET > 100 allowed for interspecies- and intraindividual variability (as in the default 10×10 uncertainty factor).

¹⁵ Technical dossier/Supplementary information February 2018/2018-01-30_SInReply_cardamom. In a letter dated 30.1.2018, the applicant FFAC confirmed 'the agreement that during the assessment of cardamom oil reference is made to the data submitted by FFAC for the assessment of chemically defined flavourings'.

Table 3: Compositional data, intake values, reference points and margin of exposure (MOE) for the individual components of cardamom oil classified according to assessment groups based on chemical groups (CGs) as defined in Annex I of Regulation (EC) No 1565/2000^(a)

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	FLAVIS No	Max conc. in the oil	Max Feed conc.	Daily Intake	Cramer Class	NOAEL ^(b)	MOE	MOET
Constituent	–	%	mg/kg	mg/kg bw per day	–	mg/kg bw per day	–	–
CG 6								
Terpineol acetate	09.830	37.3	1.865	0.1473	I	250	1,697	
α-Terpineol		2.03	0.118	0.0093	I	250	26,932	
Linalyl acetate	09.013	7.01	0.351	0.0277	I	117	4,225	
Linalool	02.013	4.62	0.231	0.0182	I	117	6,411	
Nerolidol	02.018	1.56	0.078	0.0062	I	117	18,987	
Terpinen-4-ol	02.072	2.03	0.102	0.0080	I	250	31,178	
β-Terpineol	02.097	█	0.043	0.0034	I	250	73,594	
Dihydroterpinyl acetate	n.a.	█	0.035	0.0027	I	250	91,726	
CG 6				0.2229				886
CG 16								
1,8-Cineole	03.001	24.13	1.207	0.0953	II	562.5	5,902	
CG 31, II (Acyclic alkanes)								
Myrcene	01.008	2.63	0.132	0.0104	I	44	4,235	
CG 31, III (Cyclohexene hydrocarbons)								
Limonene	01.045	4.7	0.235	0.0186	I	250	13,466	
γ-Terpinene	01.020	█	0.022	0.0017	I	250	147,189	
α-Terpinene	01.019	█	0.015	0.0011	I	250	218,245	
Terpinolene	01.005	█	0.012	0.0009	I	250	263,713	
β-Bisabolene	01.028	█	0.047	0.0037	I	250	67,331	
β-Sesquiphellandrene	n.a.	█	0.019	0.0015	I	250	171,057	
α-Zingiberene	n.a.	█	0.023	0.0018	I	3	1,688	
β-Elemene	n.a.	█	0.019	0.0015	I	3	1,999	
CG 31, III				0.0308				831
CG 31, IVe (Benzene hydrocarbons, alkyl)								
p-Cymene	01.002	█	0.080	0.0063	I	154	24,367	
CG 31, V (Bi-, tricyclic, non aromatic hydrocarbons)								
α-Pinene	01.004	2.76	0.138	0.0109	I	222	20,363	
β-Pinene	01.003	█	0.041	0.0032	I	222	69,386	
Camphene	01.009	█	0.012	0.0009	I	222	234,177	
β-Caryophyllene	01.007	█	0.010	0.0008	I	222	295,803	
Sabinene	01.059	4.78	0.239	0.0189	I	222	11,758	
α-Selinene	n.a.	█	0.016	0.0012	I	222	181,298	
CG 31, V				0.0359				6,183
CG 31, VI (macrocyclic non aromatic hydrocarbons)								
δ-Germacrene	01.042	█	0.008	0.0006	I	3	5,063	
β-Germacrene	n.a.	█	0.008	0.0006	I	3	4,747	
CG 31, VI				0.0012				2,450

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	FLAVIS No	Max conc. in the oil	Max Feed conc.	Daily Intake	Cramer Class	NOAEL ^(b)	MOE	MOET
Constituent	–	%	mg/kg	mg/kg bw per day	–	mg/kg bw per day	–	–
CG 3								
Geraniol	02.012	■	0.095	0.0075	I	345	45,969	
Geranyl acetate	09.011	■	0.095	0.0075	I	345	46,213	
Geranial	05.188	■	0.029	0.0023	I	345	153,231	
Geranic acid	n.a.	■	0.010	0.0008	I	345	436,709	
(Z)-Nerol	02.058	■	0.015	0.0011	I	345	301,179	
Farnesol	02.029	■	0.008	0.0006	I	1,000	1,582,278	
CG 3				0.0198				17,806
CG 4								
Citronellol	02.011	■	0.037	0.0029	I	50	17,106	
CG 8								
Bornyl acetate	09.017	■	0.025	0.0020	I	3	1,519	
Fenchyl alcohol (*)	02.038	■	0.019	0.0015	I	3	1,999	
<i>trans</i> -Sabinene hydrate	02.085	■	0.099	0.0078	I	222	28,529	
CG 8				0.0113				838
CG 1								
Octyl acetate	09.007	■	0.060	0.0047	I	120	25,316	
Decanoic acid	08.011	■	0.120	0.0095	I	1,000	105,485	
CG 1				0.0142				20,416

FLAVIS: the EU Flavour Information System; bw: body weight; NOAEL: no observed adverse effect level; MOE: margin of exposure; CG: chemical group.

- (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): 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.
- (*): or isobornyl acetate.

As shown in Table 3, for all the assessment groups, the MOET was ≥ 831 . Therefore, no safety concern was identified for the cardamom oil when used as a feed additive for chickens for fattening at the proposed use levels (5 mg/kg). As chickens for fattening is the species with the highest ratio of feed intake/body weight and represent the worst case scenario, the same conclusion can be extended to all animal species.

No specific proposals have been made by the applicant for the use level in water for drinking. Therefore, the FEEDAP Panel considered the same use level in water for drinking (5 mg/L) as proposed for feed (5 mg/kg). When used at 5 mg/L water for drinking, the intake of the additive via water would be 2–3 times higher than the intake via feed for poultry, pigs and rabbits (EFSA FEEDAP Panel, 2010). Considering the magnitude of the MOET (≥ 831) for all the assessment groups, a concentration of 5 mg/L water for drinking is considered safe for all animal species.

3.3.1.1. Conclusions on safety for the target species

The FEEDAP Panel concludes that cardamom essential oil from the seeds of *E. cardamomum* (L.) Maton is safe up to the proposed use level of 5 mg/kg complete feed for all animal species. A concentration of 5 mg/L water for drinking is considered safe for all animal species.

3.3.2. Safety for the consumer

Seeds of *E. cardamomum* (L.) Maton and their preparations including the essential oil are added to a wide range of food categories as spice or for flavouring purposes. Although individual consumption figures for the EU are not available, the Fenaroli's handbook of flavour ingredients (Burdock, 2010) cites intake values of 0.026 mg/kg bw per day for cardamom seed and 0.0046 mg/kg bw per day for cardamom seed oil.

The majority of the constituents identified in 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 (EFSA FEEDAP Panel, 2012c,d, 2015, 2016a–d). Although not assessed for feed use, two major components, sabinene [01.059] and sabinene hydrate [02.085], present in concentrations of > 1% of the total oil, are considered safe for use in food (EFSA AFC Panel, 2009¹⁶; EFSA CEF Panel, 2015a,b).

The constituents of cardamom essential oil are mainly terpenes and terpenoids, which are extensively absorbed, distributed, metabolised and excreted in animals. Although no data on residues in products of animal origin were made available by the applicant for any of the constituents of the essential oil, low levels of terpenoids have been reported in animal products, in particular milk (EFSA FEEDAP Panel, 2015, 2016a,c). Consequently, it has to be assumed that some residues derived from the feeding of cardamom essential oil would occur. However, the available data indicate that residues occur only in µg/kg concentrations or lower (reviewed in EFSA FEEDAP Panel, 2015, 2016a,c). Considering the reported human exposure due to direct use of cardamom seeds and their preparations in food (Burdock, 2010), it is unlikely that consumption of products from animals given cardamom essential oil at the proposed maximum use level (5 mg/kg complete feed or/and water for drinking) would significantly increase human background exposure.

3.3.2.1. Conclusions on safety for the consumer

The FEEDAP Panel concludes that the use of the essential oil from seeds of *E. cardamomum* (L.) Maton in animal feed or/and water for drinking would not appreciably increase the human exposure to the individual constituents of the oil and can therefore be considered as safe for the consumer.

3.3.3. Safety for the user

No specific data were provided by the applicant regarding the safety of the additive for users. In the absence of specific data, the FEEDAP Panel cannot conclude on the safety for the users when handling the additive.

The applicant produced a safety data sheet¹⁷ for cardamom oil where hazards for users have been identified. The applicant also proposes the use of personal protective devices to reduce the exposure of the user.

3.3.4. Safety for the environment

The additions of naturally occurring substances that will not result in a substantial increase of the concentration in the environment are exempt from further assessment (EFSA, 2008). This exemption applies to botanical preparations from plants native to Europe. However, *E. cardamomum* (L.) Maton is not native to Europe. Therefore, the safety for the environment is assessed based on the individual components of the essential oil.

At the maximum proposed use levels in feed (5 mg oil/kg feed), only the major components, i.e. terpineol acetate and 1,8-cineole, would result in concentrations higher than 1 mg/kg feed. For terpineol acetate the applicant provided evidence on the natural occurrence in European plant species well above 1 mg/kg (e.g. > 1,000 mg/kg in laurel).¹⁸ Based on its natural abundance in European plant species, 1,8-cineole has been already considered safe for the environment at concentrations higher than those expected from the use of cardamom oil in feed (EFSA FEEDAP Panel, 2012c). In

¹⁶ Sabinene hydrate [02.085]. is included in FGE.18Rev 1 as supporting substance. Sabinene hydrate [02.085] was evaluated by JECFA at the 51st meeting (1998) and no safety concern was identified at current level of intake. According to Regulation (EC) 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, no further consideration is needed for substances evaluated by JECFA before 2000 if classified as to present no safety concern.

¹⁷ Technical dossier/Supplementary Information February 2018/AAnnex_VII_SIn reply_Cardamom_oil_User_safety_conf. Hazards for skin irritation (H315), eye irritation (H319), allergic skin reaction (H317B), fatal if swallowed and enter airways (H304).

¹⁸ Technical dossier/Supplementary Information February 2018/TNO_CDG_CONF.

addition, 12 compounds (linalyl acetate, linalool, limonene, sabinene, terpinen-4-ol, α -pinene, myrcene, *p*-cymene, *trans*-sabinene hydrate, geraniol, geranyl acetate and nerolidol) would result in concentrations in feed ≥ 0.047 mg/kg feed, and would therefore need further evaluation. All substances below this concentration of 0.047 mg/kg feed are expected to produce a concentration in marine sediment lower than the threshold of Phase I of 10 μ g/kg dry weight of marine sediment. This value is also expected to result in a safe concentration for the other compartments according to the criteria of phase I risk assessment (EFSA, 2008). Compounds present at feed concentrations lower than this value are considered to be of no concern.

The applicant provided evidence that terpinen-4-ol, sabinene, *trans*-sabinene hydrate are found in concentrations greater than the maximum proposed feed levels in several plants native to EU countries (e.g. terpinen-4-ol in laurel > 1,000 mg/kg,⁸ sabinene in laurel, rosemary, sage > 100 mg/kg, and *trans*-sabinene hydrate in oregano and thyme > 500 mg/kg¹⁹), and are therefore presumed to be safe to the environment. All the other compounds have been previously assessed and considered safe for the environment at concentrations higher than those expected from the use of cardamom oil in feed. Conclusions were based on their abundance in plant materials present in European countries and/or their extensive metabolism in the target animals (EFSA FEEDAP Panel, 2012c,d, 2015, 2016a,c).

It should be noted that although some of these compounds (e.g. α -limonene) are used as active substances in pesticides (EFSA 2013b, 2014), they would not be expected to have impact on the environment when used at the maximum proposed feed level since their concentration in the feed additive is not expected to modify their natural concentration in the environment.

The use of the essential oil obtained from the seeds of *E. cardamomum* (L.) Maton in animal production at the proposed use levels is not expected to pose a risk for the environment.

3.4. Efficacy

Cardamom and its preparations are listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2010) and by FEMA with the reference number 2241.²⁰

Since cardamom and its preparations are universally 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

The FEEDAP Panel concludes that the cardamom essential oil from *E. cardamomum* (L.) Maton under consideration is safe up to the proposed use level of 5 mg/kg complete feed for all animal species. A concentration of 5 mg/L water for drinking is considered safe for all animal species

No concerns for consumer safety were identified following the application of cardamom essential oil at the maximum use level in animal nutrition.

In the absence of studies to assess the safety for the user, the FEEDAP Panel cannot conclude on the safety for the users when handling the additive.

Use in animal production of the essential oil extracted from the seeds of *E. cardamomum* (L.) Maton is not expected to pose a risk for the environment at the proposed use level.

Since cardamom 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 is considered necessary for cardamom essential oil.

5. Recommendations

The FEEDAP Panel recommends that the authorisation should apply only to the essential oil obtained from the seeds of *E. cardamomum* (L.) Maton.

The specification should ensure that the methyleugenol concentration should be as low as possible and should not exceed 0.0002% of the essential oil.

¹⁹ Technical dossier/Supplementary Information February 2018/TNO_Non-CDG_CONF.

²⁰ Technical dossier/Section IV/Page 5.

Documentation provided to EFSA/Chronology

Date	Event
05/11/2010	Dossier received by EFSA. Chemically defined flavourings from Botanical Group 09 - Zingiberales for all animal species and categories. Submitted by Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)
11/11/2010	Reception mandate from the European Commission
03/01/2011	Application validated by EFSA – Start of the scientific assessment
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. <i>Issues: analytical methods</i>
05/04/2011	Comments received from Member States
17/10/2012	Reception of supplementary information from the applicant
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
12/05/2016	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”. Discussion on the ongoing work regarding the pilot dossiers BDG08 and BDG 09
17/06/2016	Spontaneous submission of information by the applicant. <i>Issues: characterisation</i>
27/04/2017	Trilateral meeting organised by the European Commission with EFSA and the applicant FEFANA on the assessment of botanical flavourings: characterisation, substances of toxicological concern present in the botanical extracts, feedback on the pilot dossiers
24/07/2017	EFSA informed the applicant that the evaluation process restarted
22/09/2017	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended <i>Issues: characterisation, safety for target species, safety for the consumer, safety for the user and environment</i>
01/02/2018	Reception of supplementary information from the applicant
11/10/2018	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives - Scientific assessment re-started
14/05/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

AFC	EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
BDG	Botanically defined group
bw	body weight
CAS	Chemical Abstracts Service
CEF	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CG	chemical group
EEIG	European economic interest grouping
EINECS	European Inventory of Existing Chemical Substances
EMA	European Medicines Agencies
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
FID	flame ionisation detection
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 organisation
LOD	limit of detection
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
PCB	polychlorinated biphenyl

PPR EFSA Panel on Plant Protection Products and their Residues
RTL retention time locking
TTC threshold of toxicological concern
WHO World Health Organization

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for terpineol acetate in cardamom oil

In the current grouped application authorisation is sought under articles 4(1) and 10(2) for cardamom oil, turmeric oil, turmeric oleoresin, turmeric extract, turmeric tincture, ginger oil, ginger oleoresin, ginger extract and ginger tincture from botanically defined flavourings group 09 (BDG 09) as the feed additives under the category/functional group (2b) “sensory additives”/“flavouring compounds”, according to the classification system of Annex I of Regulation (EC) No 1831/2003. Authorisation is sought for the use of the feed additives for all animal species and categories.

In this report the EURL will focus exclusively on the evaluation of the suitability of analytical methods for official control of one of the nine above listed *feed additives*, namely *cardamom oil*.

According to the Applicant, the *feed additive (cardamom oil)* is a transparent colourless to pale yellow fluid liquid with characteristic odour, consisting of 30 to 42% (expressed as a relative area) of *terpineol acetate* as a phytochemical marker.

The *feed additive* is intended to be incorporated into *feedingstuffs* or drinking *water* through *flavouring premixtures* with no proposed minimum or maximum levels in *feedingstuffs* or *water*. However, the Applicant suggested the typical maximum inclusion level of the *feed additive* of 25 mg/kg *feedingstuffs*.

For the determination of *terpineol acetate* (phytochemical marker) in *cardamom oil*, the Applicant submitted an in-house developed multi-analyte method, where the identification is based on gas chromatography coupled to mass spectrometry (GC-MS), using the special “retention time locking (RTL)” methodology, and the quantification is performed using GC coupled to flame ionisation detection (FID).

However, the EURL identified the equivalent ISO 4733 standard method based on GC-FID for the determination of *terpineol acetate* in *cardamom oil*.

Based on the available performance profile, the EURL recommends for official control the ISO 4733 standard method based on gas chromatography coupled to flame ionisation detection (GC-FID) for the determination of *terpineol acetate* (phytochemical marker) in *cardamom oil*.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.