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Safety and efficacy of a feed additive consisting of a fraction of the essential oil from the fruit and leaves of *Illicium verum* Hook.f. (star anise terpenes) for use in all animal species (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 a fraction of the essential oil from the fruit and leaves of *Illicium verum* Hook.f. (star anise terpenes), when used as a feed additive for all animal species. The additive contains up to 25% estragole by specification and is obtained by a manufacturing process which results in the enrichment of this genotoxic carcinogen. This is not in line with the principles outlined in the general approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic when used as feed additives. Therefore, the FEEDAP Panel considered it was inappropriate to perform an assessment of the safety and efficacy of star anise terpenes for its use as a feed additive.

Keywords: sensory additives, flavouring compounds, *Illicium verum* Hook.f., star anise oil, star anise terpenes, estragole

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 a feed additive shall submit an application in accordance with Article 7. In addition, Article 10(2) of that Regulation specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, within a maximum of 7 years after the entry into force of this Regulation.

The European Commission received a request from Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)[2] for authorisation/re-evaluation of 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]). These preparations were deleted from the register of feed additives.[6] During the course of the assessment, this application was split and the present opinion covers one out of the 20 preparations under application: star anise terpenes produced by fractional distillation of star anise oil obtained from the fruit (or seeds) and leaves of *Illicium verum* Hook.f. for all animal species.[7]

The remaining 19 preparations belonging to botanically defined group (BDG) 02 – *Apiales/ 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 24 June 2019.

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 star anise terpenes (*I. verum*), when used under the proposed conditions of use (see Section 3.2.1.4).

1.2. Additional information

Star anise terpenes from *Illicium verum* Hook.f. 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) and foreseen for re-evaluation. It has not been assessed as a feed additive in the EU.

[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 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 parsey 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] Register of feed additives, Annex II, withdrawn by OJ L162, 10.05.2021, p. 5.
[7] The assessment of star anise oil is assessed in a separate opinion.

There is no specific EU authorisation for any *I. verum* preparation when used to provide flavour in food. However, according to Regulation (EC) No 1334/2008[8] 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.'

'Star anise (*Anisi stellati* fructus)' is described in a monograph of the European Pharmacopoeia 11.0 (PhEur, 2022a). It is defined as the dried composite fruit of *Illicium verum* Hook.f. with a minimum content of 70 mL/kg of essential oil in the anhydrous drug and with a minimum content of 86.0% of *trans*-anethole in the essential oil.

'Star anise oil (*Anisi stellati* aetheroleum)' is described in a monograph of the European Pharmacopoeia 11.0 (PhEur, 2022b). It is defined as the essential oil obtained by steam distillation from the dry ripe fruits of *Illicium verum* Hook.f.

A summary report on 'Anisi stellati fructus' has been published by the EMA Committee of Veterinary Medicinal Products (EMA, 2000).

In 2005, the European Medicines Agency (EMA) issued a public statement on the use of herbal medicinal products containing estragole, which lists *Illicium verum* Hook.f. among the plants containing estragole in the fruit and in the essential oil (EMA, 2005, revised in 2021 EMA, 2021).

Many of the individual components of star anise terpenes have been already assessed as chemically defined flavourings for use in feed and food by the FEEDAP Panel, the EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC) and the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). The list of flavouring compounds currently authorised for feed[9] and/or food[10] use, together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000,[11] and the corresponding EFSA opinion are listed in Table 1.

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

CG	Chemical group	Product (EU register name)	FLAVIS No	EFSA opinion,* year
01	Straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes	Hexan-1-ol	02.005	2013
		Hexanal	05.008	
		Heptanal	05.031	
03	α, β-Unsaturated (alkene or alkyne) straight-chain and branched chain aliphatic primary alcohols/aldehydes/ acids, acetals and ester	*(Z)*-Nerol	02.058	2016a
		Hex-2(*trans*)-enal	05.073	2019a
05	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols	Isopulegol	02.067	2020
		Heptan-2-one	07.002	2015a
		6-Methylhept-5-en-2-one	07.015	2015a, 2021a

[8] 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.

[9] 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.

[10] 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.

[11] 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
06	Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols ethers	Linalool	02.013	2012a
		α-Terpineol	02.014	
		Nerolidol	02.018	
		4-Terpinenol	02.072	
		Nerolidol[(b)]	02.232	
		(E)-3,7-Dimethylocta-1,5,7-trien-3-ol[(a)]	02.146	2011a, CEF 2015a, CEF
		Myrcenol[(a),(c)]	02.185	2011b, CEF 2015a, CEF
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	2016b
		Fenchyl alcohol	02.038	
		(1R)-1,7,7-Trimethylbicyclo [2.2.1] heptan-2-one (*d*-camphor)	07.215	
		d-Fenchone	07.159	
		Pinocarveol[(a)]	02.100	2012, CEF
		4-Isopropylcyclohex-2-en-1-one	07.172	
13	Furanones and tetrahydrofurfuryl derivatives	Linalool oxide[(d)]	13.140	2011b
14	Furfuryl and furan derivatives with and without additional side-chain substituents and heteroatoms	5-Methylfurfural	13.001	2016c
		Furfural	13.018	
		2-Acetylfurfural	13.054	2023
16	Aliphatic and alicyclic ethers	1,8-Cineole	03.001	2012c, 2021b
		2,6,6-Trimethyl-2-vinyltetrahydropyran	13.094	
18	Allylhydroxybenzenes	1-Methoxy-4-(prop-1(*trans*)-enyl) benzene (*trans*-anethole)	04.010	2011
21	Aromatic ketones, secondary alcohols and related esters	4-Methoxyphenylacetone[(a)] (anisyl methyl ketone)	07.087	2008, EFSA (AFC)
23	Benzyl alcohols, aldehydes, acids, esters and acetals	Benzaldehyde	05.013	2012d
		4-Methoxybenzaldehyde (anisaldehyde)	05.015	
		Methyl benzoate	09.725	
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	
		δ-Carene	01.029	
		δ-Cadinene[(a),(e)]	01.021	2011b, CEF
		α-Muurulene[(a),(e)]	01.052	
		β-Phellandrene[(a),(e)]	01.055	
		1,1,7-trimethyltricyclo [2.2.1.0.(2.6)] heptane (tricyclene)[(a),(e)]	01.060	

CG	Chemical group	Product (EU register name)	FLAVIS No	EFSA opinion,* year
		1,4(8),12-Bisabolatriene	01.016	2015b, CEF
		4(10)-Thujene (sabinene)[(a)]	01.059	
		cis-3,7-Dimethyl-1,3,6-octatriene *cis*-β-Ocimene[(a)]	01.064	

*: FEEDAP opinion unless otherwise indicated.
(a): Evaluated for use in food. According to Regulation (EC) 1565/2000, flavourings evaluated by JECFA before 2000 are not required to be re-evaluated by EFSA.
(b): Nerolidol [02.232]: A mixture of *(E)*- and *(Z)*-nerolidol was evaluated (EFSA FEEDAP Panel, 2012a).
(c): No longer authorised for use as flavours in food, as the additional toxicity data requested (EFSA CEF Panel, 2011a) were not submitted and the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015a).
(d): Linalool oxide [13.140]: A mixture of *cis*- and *trans*-linalool oxide (5-ring) was evaluated (EFSA FEEDAP Panel, 2012b).
(e): Evaluated applying the 'Procedure' described in the Guidance on the data required for the risk assessment of flavourings to be used in or on food (EFSA CEF Panel, 2010). No longer authorised for use as flavours in food, as the additional toxicity data requested (EFSA CEF Panel, 2011b) were not submitted and the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015b).

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[12] in support of the authorisation request for the use of star anise terpenes from *I. verum* as a feed additive. The dossier was received on 7 June 2023 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00399.[13]

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

Many of the components of the star anise terpenes 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 preparations belonging to BDG 2, including the current one under assessment.[14]

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 animal feed. The evaluation report is related to the methods of analysis for each feed additive included the group BDG 02 (Apiales and Austrobaileyales). During the assessment, the EURL issued a partial report[15] and an addendum of the report.[16] In particular, for the characterisation of *anise star terpenes*, the EURL recommended methods based on gas chromatography with flame ionisation detection (GC-FID) for the quantification of the phytochemical marker 1-methoxy-4-(prop-1(*trans*)-enyl)benzene (hereinafter referred as to *trans*-anethole) in the additive.[17]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of star anise terpenes from *I. verum* is in line with the principles laid down in Regulation (EC) No 429/2008[18] and

[12] FEED dossier reference: FAD-2010-0221.
[13] The original application EFSA-Q-2010-01286 was split on 6 July 2023 and a new EFSA-Q-2023-00399 was generated.
[14] Technical dossier/Supplementary information/Letter dated 29/04/2021.
[15] 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.
[16] 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.
[17] The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0221_en.
[18] 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.

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, 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, 2019b), 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), General approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic (EFSA FEEDAP Panel, 2021c).[19]

The FEEDAP Panel notes that the additive under assessment is obtained by a manufacturing process, which results in the enrichment of a genotoxic and carcinogenic compound (estragole). This is not in line with the principles outlined in the general approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic when used as feed additives.

3. Assessment

The additive under assessment, star anise terpenes, is obtained by fractional distillation of star anise essential oil produced from the fruit and leaves of *Illicium verum* Hook.f., and is intended for use as a sensory additive (functional group: flavouring compounds) in feed and water for drinking for all animal species.

3.1. Origin and extraction

Illicium verum Hook.f. is an evergreen tree belonging to the Schisandraceae family, native to Vietnam and China. It is widely grown in the region for its characteristic fruits which have a long history of culinary and traditional medical uses. The individual fruit are star-shaped, consisting of a ring of reddish-brown carpels each containing a single seed, and are generally harvested just before ripening. The harvested fruit are commonly referred to as 'star anise', reflecting both their shape and their sensory profile, which closely resembles that of true anise fruit (*Pimpinella anisum* L.). For this reason, star anise fruit is often used as a cheaper substitute for anise fruit in food, alcoholic beverages and household products. The term 'star anise' is used to describe both the plant, *Illicium verum* (also called Chinese star anise), and its fruit. The fruit of Chinese star anise should not be confused with the highly poisonous fruit of Japanese star anise (*Illicum anisatum* L.) which resemble each other closely (PhEur Commentary, 2020).

There are no references to the use of star anise leaves as a spice or for traditional medical purposes in the standard literature.

The additive under assessment, star anise terpenes, is obtained by fractional distillation of star anise oil produced from the fruits and leaves from the plant species *Illicium verum* Hook. f. (sourced from China).

3.2. Characterisation

3.2.1. Characterisation of star anise terpenes

The additive under assessment, star anise terpenes, is a pale yellow to yellow mobile liquid, with a characteristic aroma (sweet spicy anise). In five recent batches of the additive (all originating from China), the refractive index (20°C) ranged between 1.4802 and 1.4907 (specification: 1.475–1.560),

[19] https://www.efsa.europa.eu/sites/default/files/2021-05/general-approach-assessment-botanical-preparations-containing-genotoxic-carcinogenic-compounds.pdf.

the density (20°C) between 882 and 898 kg/m^3 (specification: 860–930 kg/m^3), the optical rotation (20°C, three batches) between 3.4° and 4.1° (specification: 2.0–15.0).[20] The additive star anise terpenes is identified with the Chemical Abstracts Service (CAS) number 68952-43-2,[21] and the Council of Europe (CoE) number 238.

The specifications for star anise terpenes used by the applicant are based on those developed by the International Organisation for Standardization (ISO) 11016:1999 for essential oil of star anise (*I. verum*),[22] adapted to reflect the concentrations of the main volatile components of the additive (Table 2). Four components contribute to the specifications as shown in Table 2, with *trans*-anethole selected as the phytochemical marker. Analysis of three batches of the additive showed compliance with these specifications when analysed by GC-FID and expressed as percentage of gas chromatographic peak area (% GC area).[23]

Table 2: Major constituents of the fraction of the essential oil from the fruit and leaves of *Illicium verum* Hook.f. (star anise terpenes) as defined by specifications: batch to batch variation based on the analysis of four batches by gas chromatography with flame ionisation detector. 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		
			Specification[(a)]	Mean	Range
Estragole[(b)]	140-67-0	04.011	< 25	23.59	23.3–24.3
Limonene	5989-27-5	01.001	5–25	22.79	22.7–23.0
Linalool	78-70-6	02.013	1–15	10.18	9.9–10.6
trans-Anethole	4180-23-8	04.010	5–15	11.47	11.3–11.9
Total				67.39	67.26–67.47[(c)]

EU: European Union; CAS No: Chemical Abstracts Service number; FLAVIS No: EU Flavour Information System numbers.
(a): Specifications defined based on GC-FID analysis.
(b): Substance which shall not be added as such to food (Annex III), maximum level in food is set by Regulation (EC) No 1334/2008, including dairy products (50 mg/kg), processed fruits, vegetables (incl. mushrooms, fungi, roots, tubers, pulses and legumes), nuts and seeds (50 mg/kg), fish products (50 mg/kg) and non-alcoholic beverages (10 mg/kg).
(c): The values given for the total are the lowest and the highest values of the sum of the components in the three batches analysed.

The FEEDAP Panel notes that 'star anise terpenes' contains a concentration of estragole, which is 4- to 12-fold higher than the concentration of estragole (2–6%) in essential oils from the fruit of *I. verum* (see Section 3.2.1.1).

The applicant provided a full characterisation of the volatile constituents in four additional batches obtained by gas chromatography coupled with mass spectrometry (GC–MS).[23] In total, up to 88 constituents were detected, 83 of which were identified and accounted on average for 98.6% (97.9–99.0%) of the % GC area. The four compounds indicated in the product specifications account for about 51.5% on average (range 34.1–64.0%) of % GC area. Besides the four compounds indicated in the product specifications, 39 other compounds were detected at individual levels > 0.1% and are listed in Table 3. These 43 compounds, each making up > 0.1% of the composition, together accounted on average for 97.2% (95.9–98.1%) of the GC area. The remaining 40 compounds (ranging between 0.004% and 0.1%) and accounting for 1.4% of the % GC area are listed in the footnote.[24]

[20] Technical dossier/Supplementary information April 2023/Annex_II_anise_star_terpenes_CoA_chrom.
[21] The following entries were found at https://echa.europa.eu/home. Star anise, Illicium verum, ext. – Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from Illicium verum, Illiciaceae. EINECS: 283-518-1 CAS: 84650-59-9.
[22] Technical dossier/Supplementary information April 2023/Annex_III_SIn_reply_anise_star_oil_ ISO.
[23] Technical dossier/Supplementary information April 2023/Annex_II_anise_star_oil_CoA_chromatogram.
[24] Additional constituents: 20 components ≤ 0.1 and > 0.05%: globulol, γ-selinene, methyl benzoate, aromadendrene, pinocarveol, furfural, 2,6,6-trimethyl-2-vinyltetrahydropyran, cubeban-11-ol, *(Z)*-nerol, palustrol, α-cadinene, benzaldehyde, isopulegol, 5-methylfurfural, *ortho*-cymene, bicyclogermacrene, spathulenol, (1R)-1,7,7-trimethylbicyclo[2.2.1]heptan-2-one, α-calacorene, *cis*-para-2-menthen-1-ol, 20 components ≤ 0.05 and ≥ 0.004%: pinocarvone, rosifoliol, α-fenchene, hexanal, fenchyl alcohol, trans-carveol, *(E)*-3,7-dimethylocta-1,5,7-trien-3-ol, (3R-*trans*)-3-methyl-6-(1-methylvinyl)cyclohexene, sesquisabinene, 6-methylhept-5-en-2-one, *trans*-sabinene hydrate, *(E,Z)*-alloocimene, *trans*-para-2-menthen-1-ol, hex-2 (*trans*)-enal, hexan-1-ol, 1,1,7-trimethyltricyclo[2.2.1.0.(2.6)]heptane, myrcenol, heptan-2-one, 2-acetylfuran and heptanal.

Based on the available data on the characterisation, star anise terpenes is considered a fully defined mixture (EFSA SC, 2019a).

Table 3: Constituents of the fraction of the essential oil from the fruit and leaves of *Illicium verum* Hook.f. (star anise terpenes) accounting for > 0.1% of the composition (based on the analysis of four 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	Range
Estragole[(a)]	140-67-0	04.011	18.11	13.46–24.40
Limonene	5989-27-5	01.001	17.86	8.14–23.04
Linalool	78-70-6	02.013	7.98	3.91–11.88
trans-Anethole	4180-23-8	04.010	7.51	0.64–10.60
α-Pinene (pin-2(3)-ene)	80-56-8	01.004	7.18	5.56–11.21
β-Phellandrene	555-10-2	01.055	4.83	3.37–8.14
β-Vetivenene	–	–	4.74	4.74[(a)]
α-Phellandrene	99-83-2	01.006	4.03	2.13–6.39
δ-3-Carene	13466-78-9	01.029	3.92	3.40–4.54
p-Cymene (1-isopropyl-4-methylbenzene)	99-87-6	01.002	3.68	3.03–4.50
(Z)-Anethole	25679-28-1	–	3.46	1.81–7.15
d-Fenchone	4695-62-9	07.159	3.46	1.53–5.39
1,8-Cineole	470-82-6	03.001	3.22	2.05–4.85
4-Terpinenol	562-74-3	02.072	2.74	1.20–6.17
Myrcene	123-35-3	01.008	1.31	1.14–1.67
Sabinene (4(10)-thujene)	3387-41-5	01.059	0.69	0.48–0.98
γ-Terpinene	99-85-4	01.020	0.82	0.61–1.21
β-Pinene (pin-2(10)-ene)	127-91-3	01.003	0.79	0.56–1.10
α-Terpinene	99-86-5	01.019	0.75	0.48–1.16
Terpinolene	586-62-9	01.005	0.72	0.02–1.44
Viridiflorene	21747-46-6	–	0.56	0.56–0.56
α-Terpineol	98-55-5	02.014	0.56	0.09–1.13
α-Copaene	3856-25-5	–	0.52	0.44–0.65
1,4(8),12-Bisabolatriene	495-62-5	01.016	0.49	0.06–0.92
Nerolidol	7212-44-4	02.018	0.39	0.39[(a)]
trans-para-1(7),5-menthadien-2-ol	95259-30-6	–	0.32	0.07–0.95
4-Isopropylcyclohex-2-en-1-one	500-02-7	07.172	0.32	0.05–0.81
Anisaldehyde (4-methoxybenzaldehyde)	123-11-5	05.015	0.46	0.16–0.87
Camphene	79-92-5	01.009	0.30	0.12–0.54
β-Caryophyllene	87-44-5	01.007	0.28	0.10–0.45
δ-Cadinene	29350-73-0	01.021	0.27	0.27[(a)]
Borneol	507-70-0	02.016	0.26	0.12–0.61
trans-3,7-Dimethyl-1,3,6-octatriene	3779-61-1	–	0.23	0.18–0.28
cis-Linalool oxide (5-ring)	5989-33-3	–	0.21	0.14–0.36
α-Thujene	2867-05-2	–	0.18	0.14–0.23
Epoxyanethole	51410-46-9	–	0.17	0.13–0.20
α-Muurolene	10208-80-7	01.052	0.16	0.16[(a)]
(Z)-α-Bergamotene	18252-46-5	–	0.16	0.05–0.27
γ-Cadinene	1460-97-5	–	0.15	0.15
4-Methoxyphenylacetone	122-84-9	07.087	0.15	0.12–0.18
(E)-α-bergamotene	13474-59-4	–	0.14	0.02–0.45

Constituent EU register name	CAS No	FLAVIS No	% GC area	
			Mean	Range
α-Cubebene	17699-14-8	–	0.14	0.03–0.27
cis-3,7-Dimethyl-1,3,6-octatriene	3338-55-4	01.064	0.12	0.07–0.23
Total			45.79	34.15–63.02(b)

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

3.2.1.1. Substances of concern

The applicant performed a literature search regarding substances of concern and chemical composition of the plant species *I. verum* and its preparations.[25] Phenylpropanoids e.g. *trans*-anethole (75–90%), estragole (methylchavicol, 0.34–5.04%) and safrole (0.14%) are reported in the EFSA Compendium of botanicals as substances of concern for the essential oil from the fruit of *I. verum* (EFSA, 2012).[26] The presence of safrole in star anise oil reported in the EFSA compendium of botanicals is based on two references, Council of Europe (2000) and Tisserand and Young (2014). However, the potential presence of safrole in unadulterated star anise oil from the fruit is waived in the PhEur Commentary (2020): '*Previous research suggested the presence of safrole in star anise oil, but this proved to be confounding due to the fact that safrole has approximately the same Rf value as foeniculin on the TLC plate. Safrole is a typical component of the oil from shikimi fruit, the fruit of Illicium anisatum L., also known as an adulterant of star anise fruit; the oil of these fruits could also get into the star anise oil if they were mixed up*'.

Several publications retrieved by the applicant consistently reported the occurrence of estragole (2–6%) in essential oils from the fruit of *I. verum* (e.g. Dwivedy et al., 2018; Li et al., 2020; EMA, 2021). Two publications also reported the presence of methyleugenol (0.12%) and safrole (0.21%) in essential oils from star anise fruit obtained by different manufacturing processes and containing, respectively, 10% and 14.4% estragole (Nie et al., 2021; Sabry et al., 2021).

No literature was made available describing the composition/substances of concern in oil obtained from the leaves of *I. verum*.

An analysis of the seven batches of star anise terpenes under assessment confirmed the presence of estragole in all batches (13.5–24.4%). Safrole was not detected in the additive under assessment (LOD, 0.001%).

The FEEDAP Panel notes that the concentration of estragole is enriched 4- to 12-fold in star anise terpenes compared to the star anise oil from which the additive is obtained.

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 on the presence of these impurities. Since the additive is produced by fractional distillation of star anise oil, the likelihood of any measurable carry-over of all the above-mentioned elements is considered low, except for mercury.

3.2.1.3. Shelf-life

The typical shelf-life of star anise terpenes 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).[27] However, no data supporting this statement were provided.

3.2.1.4. Conditions of use

The additive is intended to be added to feed and water for drinking for all animal species without a withdrawal period. Maximum use levels in complete feed were proposed for the animal species and

[25] Technical dossier/Supplementary information April 2023/Literature search_anise_star_oil.
[26] Online version: https://www.efsa.europa.eu/en/data-report/compendium-botanicals.
[27] Technical dossier/Section II.

categories listed in Table 4. No use level has been proposed by the applicant for other target species and for the use in water for drinking.

Table 4: Conditions of use for star anise terpenes obtained by fractional distillation of the essential oil from the fruits and leaves of *Illicium verum* Hook.f.: Maximum proposed use levels in complete feed for certain target animal categories

Animal category	Maximum proposed use level (mg/kg complete feed)
Long-living and reproductive animals	
Laying hen	0.10
Sow lactating	0.25
Dairy cow	0.25
Sheep/goat	0.35
Horse	0.40
Rabbit	0.15
Dog	0.45
Cat	0.35
Ornamental fish	1.50
Species for fattening	
Chicken for fattening	1.3
Turkey for fattening	1.7
Piglet	2.4
Pig for fattening	2.8
Veal calf (milk replacer)	6.0
Cattle for fattening	5.2
Sheep/goat	5.2
Horse	5.2
Rabbit	2.1
Salmon	6.0

3.2.2. Safety and efficacy

Estragole, a compound with experimentally proven genotoxicity and carcinogenicity in rodents (as reviewed in EMA, 2021), is one of the main components of the additive under assessment. The data submitted by the applicant showed that the production process of the additive star anise terpenes results in an enrichment of the genotoxic carcinogen estragole from star anise oil. This does not accord with the principles outlined in the general approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic when used as feed additives (EFSA FEEDAP Panel, 2021a). Any manufacturing processes of botanical feed additives should avoid selective extraction and enrichment of genotoxic and/or carcinogenic substances and should aim at the reduction of these substances.

The FEEDAP Panel notes that the margin of exposure (MOE) approach was originally designed to allow an assessment of additives with impurities with genotoxic/carcinogenic activity (EFSA, 2005; EFSA SC, 2012), and was later adapted to the assessment of the safety for the target species of feed additives of botanical origin in which genotoxic and/or carcinogenic substances cannot be fully avoided (EFSA FEEDAP Panel, 2021a). In the present feed additive, terpenes and estragole, a genotoxic carcinogen, are selectively extracted and substantially enriched. Therefore, the Panel considers it inappropriate to perform an assessment of the safety and the efficacy of this additive.

4. Conclusions

The additive under assessment is obtained by a manufacturing process which results in the enrichment of a genotoxic carcinogen. This does not accord with the principles outlined in the general approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic when used as feed additives. Therefore, the

FEEDAP Panel considers it inappropriate to perform an assessment of the safety and efficacy of star anise terpenes for its use as a feed additive.

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
28/10/2020	Reception of supplementary information from the applicant (partial submission: anise tincture included in another assessment) – 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*)
11/04/2023	Reception of supplementary information from the applicant (partial submission: star anise oil and star anise terpenes)
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*)
07/06/2023	The application was split and a new EFSA-Q-2023-00399 was assigned to the preparations included in the present assessment
08/06/2023	Scientific assessment re-started
26/09/2023	Opinion adopted by the FEEDAP Panel on anise oil and anise tincture (EFSA-Q-2023-00399). 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 Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food
BDG	Botanically defined group
CAS	Chemical Abstracts Service
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	Flavour 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
FLAVIS-No	FLAVIS number
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC–MS	gas chromatography–mass spectrometry
ISO	International standard organisation
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOQ	Limit of quantification
PhEur	European Pharmacopoeia
sb	Solvent-based
SC	EFSA Scientific Committee
WHO	World Health Organization