Safety and efficacy of a feed additive consisting of an essential oil obtained from the flowering aerial parts of Thymus vulgaris L. and/or Thymus zygis L. (thyme oil) for use in all animal species (FEFANA asbl)

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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of an essential oil obtained from the flowering aerial parts of *Thymus vulgaris* L. and/or *Thymus zygis* L. (thyme oil) for use in all animal species (FEFANA asbl)

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

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 from the flowering aerial parts of *Thymus vulgaris* L. and/or *Thymus zygis* L. (thyme oil) when used as a sensory additive in feed and in water for drinking for all animal species. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that the additive under assessment is considered safe up to the maximum proposed use level in complete feed of 100 mg/kg for pigs for fattening, sows, veal calves, cattle for fattening, dairy cows, sheep/goats, horses, salmonids, dogs and ornamental fish. For the other target species, the calculated safe concentrations in complete feed were: 48 mg/kg for chickens for fattening, 72 mg/kg for laying hens, 64 mg/kg for turkeys for fattening, 86 mg/kg for piglets, 76 mg/kg for rabbits and 38 mg/kg for cats. These conclusions were extrapolated to other physiologically related species. For any other species, the additive is safe at 38 mg/kg complete feed. The FEEDAP Panel considered that the use in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed. The use of the additive in animal feed under the proposed conditions of use is safe for the consumer and the environment. Regarding user safety, the oil under assessment should be considered as an irritant to skin and eyes and as a dermal and respiratory sensitiser. Exposure of users by any route is considered a risk. Since thyme oil is recognised to flavour food and its function in feed would be essentially the same as that in food, no further demonstration of efficacy was necessary.

KEYWORDS

efficacy, flavouring compounds, safety, sensory additives, thyme oil, thymol, *Thymus vulgaris* L., *Thymus zygis* L.

CONTENTS

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 41 additives (king of bitter extract, thyme leaved gratiola tincture, devils claw extract, devils claw tincture, lavender oil, lavender tincture, spike lavender oil, melissa oil, balm leaves extract, mentha arvensis/corn mint oil, pennyroyal oil, spearmint oil, peppermint oil, peppermint tincture, basil oil, basil tincture, olive extract, marjoram oil, oregano oil, oregano tincture, patchouli oil, rosemary oil, rosemary oleoresin, rosemary extract, rosemary tincture, Spanish sage oil, sage oil, sage tincture, clary sage oil, savory summer oil, savory summer tincture, Pau darco tincture, thymus, origanum oil, thyme oil, thyme oleoresin, thyme extract, thyme tincture, lilac chastetree extract, lilac chastetree tincture, Spanish marjoram oil and wild thyme tincture) belonging to botanically defined group (BDG) 01 – Lamiales, when used as a feed additive for all animal species (category: sensory additives; functional group: flavouring compounds). During the assessment, the applicant withdrew the applications for 12 additives.[3] These additives were deleted from the register of feed additives.[4] In addition, during the course of the assessment, the application was split and the present opinion covers only one out of the remaining 29 additives under application: thyme oil from *Thymus vulgaris* L. and *Thymus zygis* L.[5] for use in all animal species.

The remaining 28 additives belonging to botanically defined group (BDG) 01 – Lamiales, under application are assessed in separate opinions.

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority deleted (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive) and under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 1 June 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 feed additive consisting of an essential oil from the flowering aerial parts of *T. vulgaris* and *T. zygis* when used under the proposed conditions of use (see Section 3.3.3).

1.2 | Additional information

Thyme oil from *T. vulgaris* L., *T. zygis* 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.

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[6] in support of the authorisation request for the use of an essential oil from *T. vulgaris* and/or *T. zygis* as a feed additive. The dossier was received on 26 June 2025 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2025-00403.[7]

[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]Thyme leaves gratiola tincture, spike lavender oil, melissa oil, pennyroyal oil, basil oil and savory summer oil (27 February 2019); Spanish majoram oil (28 September 2023); lilac chastetree extract and savory summer tincture (8 July 2024); devils claw extract (wb), balm leaves extract (sb), olive extract (sb) (16 December 2024).
[4]Register of feed additives, Annex II, withdrawn by OJ L162, 10.5.2021, p. 5.
[5]Accepted names: *Thymus vulgaris* L., *Thymus zygis* L.
[6]Dossier reference: FAD-2010-0137.
[7]The original application EFSA-Q-2010-0137 was split on 26/06/2025 and a new EFSA-Q-2025-00403 was generated.

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

Many of the components of the essential oil under assessment have been already evaluated by the FEEDAP Panel as chemically defined flavourings (CDGs). The applicant submitted a written agreement to reuse the data submitted for the assessment of chemically defined flavourings (dossiers, publications and unpublished reports) for the risk assessment of preparations belonging to BDG 01, including the current one under assessment.[8]

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the phytochemical markers in the additive. During the assessment, upon request of EFSA, the EURL issued two partial reports.[9] The additive under assessment is included in the second partial report. In particular, the EURL recommended a method based on gas chromatography with flame ionisation detection (GC–FID) for the quantification of the phytochemical marker *thymol* in *thyme oil*.[10]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of thyme oil from *T. vulgaris* and/or *T. zygis* is in line with the principles laid down in Regulation (EC) No 429/2008[11] and the relevant guidance documents: Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (EFSA Scientific Committee, 2009), Compendium of botanicals,[12] Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019), Guidance on the assessment of the safety of feed additives for the users (EFSA FEEDAP Panel, 2023), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024), Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee, 2019), Statement on the genotoxicity assessment of chemical mixtures (EFSA Scientific Committee, 2019), Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA Scientific Committee, 2019).

3 | ASSESSMENT

The additive under assessment, thyme oil, is an essential oil obtained from the fresh flowering aerial parts of *T. vulgaris* L., *T. zygis* L. or their mixtures. 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

T. vulgaris L. (common thyme or garden thyme) is a small, semi-evergreen, perennial shrub belonging to the family Lamiaceae. It is characterised by its horizontal and upright growth habit with stems becoming woody with age, its small grey/green leaves (up to 5 mm in length) and branches terminated in season by purple/pink flowers. This species is native to France, Italy and Spain, but is now commonly found throughout mainland Europe, the UK and parts of north Africa, valued for use as an ornamental garden plant and culinary herb. *T. vulgaris*, like many *Thymus* species, readily hybridise when flowering periods overlap. As a result, in addition to the three recognised sub-species, numerous hybrids and cultivars exist.

T zygis L. (Spanish thyme) is also a small perennial shrub of the Lamiaceae, closely resembling *T. vulgaris* but differing in the size of its leaves (up to 8 mm) and its white flowers. Unlike *T. vulgaris* it has a more restricted geographical distribution being native to the Iberian Peninsula, Morocco and Algeria, with no evidence of subsequent introductions in the wild elsewhere. It is also the primary source of most thyme essential oil, with the bulk being produced in Spain.

[8]Technical dossier/Supplementary information August 2024/Letter dated 27/08/2024.

[9]Additives included in the first partial report: Spanish sage oil, peppermint oil, thymus origanum oil, patchouli oil, clary sage oil, lavender oil and sage oil; additives included in the second partial report: cornmint oil, spearmint oil, thyme oil, rosemary oil, marjoram oil, rosemary tincture, basil tincture, lavender tincture, peppermint tincture, sage tincture and wild thyme tincture.

[10]Evaluation report received on 18/6/2025 and available on the EU Science Hub https://joint-research-centre.ec.europa.eu/reports-and-technical-documentation/fad-2010-0137_en.

[11]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.

[12]Online version: https://www.efsa.europa.eu/en/data-report/compendium-botanicals.

The additive is extracted from the flowering aerial parts (fresh leaves, flowering tops and twigs) of *T. vulgaris* and/or *T. zygis* by steam distillation. The volatile constituents are condensed and then separated from the aqueous phase by decantation.

3.2 | Uses other than feed flavouring

There is no specific EU authorisation for any *T. vulgaris* and/or *T. zygis* preparation when used to provide flavour in food. However, according to Regulation (EC) No 1334/2008[13] 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.'

'Thyme (Thymi herba)' and 'Thyme oil, thymol type (Thymi typo thymolo aetheroleum)' from *T. vulgaris* L., *T. zygis* L. or their mixtures are described in monographs of the European Pharmacopoeia 11.0 (PhEur, 2022a, 2022b) and of the European Medicines Agency (EMA, 2013a, 2013b, 2013c, 2020a, 2020b, 2020c) for medicinal uses.

3.3 | Characterisation

3.3.1 | Characterisation of the thyme oil

The essential oil is obtained from the flowering aerial parts of *T. vulgaris* and/or *T. zygis* sourced from Europe and is a clear, yellow to brown, mobile liquid with a characteristic odour. Thyme oil is identified with the single Chemical Abstracts Service (CAS) number 8007-46-3, the European Community (EC) number 284-535-7/285-397-0,[14] the Flavor Extract Manufacturers Association (FEMA) number 3064/3065 and the Council of Europe (CoE) number 456/457. In nine batches of the additive, the refractive index (20°C) fell within the range 1.500–1.5021, the density (20°C) ranged between 925 and 929 kg/m^3 in three batches, and the optical rotation (20°C) between −0.73° and −2.0° in six batches.[15]

The applicant provided a full analysis of seven batches of thyme oil obtained from *T. vulgaris* and six batches from *T. zygis* using gas chromatography–mass spectrometry (GC–MS) and expressed as percentage of gas chromatographic peak area (% GC area).[16] Table 1 summarises the analytical results for the individual essential oils obtained from different species of origin (*T. vulgaris* or *T. zygis*). The results indicate that the two oils are similar, when considering the 28 components detected at individual levels of > 0.1% of the GC area. Based on this comparison, the FEEDAP Panel considers that there is no need for a separate assessment for the two oils. Therefore, the current assessment covers thyme oil from *T. vulgaris, T. zygis* or their mixtures.

TABLE 1 Comparison of the constituents of thyme oil from *Thymus vulgaris* L. (seven batches) and *Thymus zygis* L. (six batches) analysed by gas chromatography–mass spectrometry (GC–MS). The content of each constituent is expressed as the area per cent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%. Constituents accounting for > 0.1% of the % GC area are shown in the Table.

Constituent			% GC area			
			Thymus vulgaris L.		*Thymus zygis* L.	
EU register name	CAS No	FL-No	Mean	Range	Mean	Range
Thymol	89-83-8	04.006	53.71	47.78–57.65	51.04	48.50–54.75
p-Cymene (1-isopropyl-4-methylbenzene)	99-87-6	01.002	17.87	15.16–21.07	17.97	15.31–19.66
γ-Terpinene	99-85-4	01.020	8.83	7.38–10.34	7.71	6.09–8.90
Linalool	78-70-6	02.013	3.59	2.94–4.63	3.81	3.04–4.74
Carvacrol	499-75-2	04.031	3.95	2.81–4.56	4.46	3.94–5.27
β-Caryophyllene	87-44-5	01.007	1.70	1.09–2.41	1.77	1.58–1.94
d,l-Borneol	507-70-0	02.016	1.71	0.90–3.13	1.13	0.77–1.86

(Continues)

[13]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.

[14]The following entries were found at https://echa.europa.eu/home: Thyme, *Thymus vulgaris*, ext. (Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Thymus vulgaris*, Labiatae), EC 284-535-7; CAS 84929-51-1; Thyme, *Thymus zygis*, ext. (Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Thymus zygis*, Labiatae), EC 285-397-0, CAS 85085-75-2.

[15]Technical dossier/Supplementary information July 2024/Annex_II_SIn_reply_ Thyme_oil_COA_chrom.

[16]Technical dossier/Supplementary information July 2024/Annex_II_SIn_reply_ Thyme_oil_COA_chrom.

TABLE 1 (Continued)

Constituent			% GC area			
			Thymus vulgaris L.		*Thymus zygis* L.	
EU register name	CAS No	FL-No	Mean	Range	Mean	Range
α-Terpinene	99-86-5	01.019	1.28	0.70–1.80	1.47	0.86–2.06
Myrcene	123-35-3	01.008	1.21	1.02–1.47	1.50	1.08–2.11
α-Pinene (pin-2(3)-ene)	80-56-8	01.004	1.13	0.15–2.26	1.35	1.07–1.62
4-Terpinenol	562-74-3	02.072	1.09	0.80–1.68	0.96	0.80–1.07
α-Thujene	2867-05-2	–	0.38	0–1.00	0.85	0.48–1.50
Camphene	79-92-5	01.009	0.65	0.07–0.95	0.52	0.46–0.61
d-Limonene[1]	5989-27-5	01.045	0.33	0.27–0.47	0.51	0.30–0.99
β-Pinene (pin-2(10)-ene)	127-91-3	01.003	0.39	0.11–0.82	0.34	0.22–0.65
α-Terpineol	98-55-5	02.014	0.25	0.13–0.42	0.41	0.09–0.80
Carvacryl methyl ether	6379-73-3	04.059	0.26	0–0.45	0.15	0–0.36[3]
Camphor[2]	76-22-2	–	0.31	0–0.66[3]	0.10	0.03-0.20
γ-Terpineol	586-81-2	–	–	–	0.11	0–0.25[3]
β-Phellandrene	555-10-2	01.055	0.20	0.14–0.32	0.13	0.18–0.24
Terpinolene	586-62-9	01.005	0.11	0.07–0.18	0.26	0.22–0.33
trans-Sabinene hydrate	17699-16-0	–	0.06	0–0.15	0.19	0.13–0.32
α-Phellandrene	99-83-2	01.006	0.14	0–0.20[4]	0.21	0.12-0.33
β-Caryophyllene epoxide	1139-30-6	16.043	0.02	0–0.05[3]	0.20	0.12-0.38
5-Methyl-2-propylphenol	31143-55-2	–	–	–	0.06	0–0.16[3]
3,7,10-Humulatriene	6753-98-6	01.043	0.01	0–0.4[3]	0.16	0.09-0.21
1,8-Cineole	470-82-6	03.001	0.03	0–0.08[3]	0.13	0.04-0.20
Thymyl methyl ether (1-isopropyl-2-methoxy-4-methylbenzene)	1076-56-8	04.043	–	–	0.10	0–0.21
Total			99.1[5]	98.2-99.6[6]	97.6[5]	96.3-98.4[6]

Abbreviations: CAS No., Chemical Abstracts Service number; EU, European Union; FLAVIS No, EU Flavour Information System number.

[1]Stereochemistry not given, however considering that the naturally occurring limonene is typically *d*-limonene, it is assumed that this form also occurs in thyme oil.

[2]Present in the additive as a mixture of enantiomers (*d,l*-camphor), the ratio between *d*- and *l*-stereoisomers is not given.

[3]Detected in three batches.

[4]Detected in five batches.

[5]The value given for the Total (mean) is the mean of the sum of the constituents in the individual batches analysed.

[6]The values given for the Total (range) are the lowest and the highest values of the sum of the constituents in the individual batches analysed.

When considering the overall dataset (*T. vulgaris* & *T. zygis*), up to 91 peaks were detected and identified in the chromatograms, accounting for on average 99.3% (98.3%–100.0%) of the GC area. The 28 compounds detected at individual levels of > 0.1% and listed in Table 1 together account on average for 98.4% (96.3%–99.6%) of the GC area. The remaining 63 compounds (ranging between 0.09% and 0.001%) and accounting for 0.9% of the GC area are listed in the footnote.[17] Based on the available data on the characterisation, thyme oil is considered a fully characterised mixture, as defined by the EFSA Scientific Committee (2019).

The product specifications used by the applicant are based on the standard developed by the International Organization for Standardization (ISO) 19817:2017 (Essential oil of thyme [*T. vulgaris* L. and *T. zygis* L.], thymol type)[18] and by the European Pharmacopoeia (PhEur 01/2008:1838)[19] adapted to reflect the concentrations of selected volatile components. Four components contribute to the specifications as shown in Table 2, with thymol selected as the phytochemical marker. Analysis of 10 batches of the additive obtained either from *T. vulgaris* and/or *T. zygis* showed compliance with the specifications when analysed by GC-FID and expressed as percentage of gas chromatographic peak area (% GC area).[20]

[17]Additional constituents ($n = 63$) between < 0.09 and ≥ 0.004%: *(1R,2R,5S)*-5-isopropenyl-2-methylcyclopentanecarboxaldehyde, aromadendrene, 2-(3-methyl-2-cyclopenten-1-yl)-2-methylpropionaldehyde, isothujol, 1-isopropenyl-4-methylbenzene, linalool oxide, δ-3-carene, fenchone, 2-(4-methylphenyl)propan-2-ol, viridiflorene, 1,1,7-trimethyltricyclo[2.2.1.0.(2.6)]heptane (tricyclene), β-bisabolene, spathulenol, 3,7-dimethylocta-1,5,7-trien-3-ol, (+)-δ-cadinene, *trans*-3,7-dimethylocta-2,6-dienal (citral), fenchyl alcohol, octan-3-one, *cis*-dihydrocarvone, thymyl acetate, *d,l*-bornyl formate, *d,l*-bornyl acetate, γ-cadinene, geraniol, *trans*-3,7-dimethyl-1,3,6-octatriene (*trans*-β-ocimene), alloaromadendrene, *cis*-linalool oxide (5-ring), neral, geranyl butyrate, carvacryl acetate, *trans*-sabinol, 4-hydroxy-4-methylpentan-2-one, γ-muurolene, *(Z)*-nerol, eugenol, 4-isopropylbenzaldehyde, isocadinene, calamenene, pin-2-en-4-one (verbenone), α-copaene, α-muurolene, hex-3(*cis*)-en-1-ol, 4-terpinenyl acetate, *m*-cymene, carvone, *d,l*-isoborneol, 4-isopropylbenzyl alcohol, β-gurjenene, β-terpineol, octan-3-ol, citronellol, methyl benzoate, 6-methylhept-5-en-2-one, hexan-1-ol, furfural, humulene oxide II, 1-terpinenol, neryl isovalerate, methyl 2-methylbutyrate, geranyl propionate, 2,4-thujadiene, *cis*-3,7-dimethyl-1,3,6-octatriene (*cis*-β-ocimene) and β-cadinene.

[18]Technical dossier/Supplementary information July 2024/Annex_IIIa_Sln_reply_Thyme_ oil_ISO_19817_2017.

[19]Technical dossier/Supplementary information July 2024/Annex_IIIb_Sln_reply_Thyme_ oil_Eur.Ph. 01-2012-1347.

[20]Technical dossier/Supplementary information July 2024/BDG_01_Sln_reply_ Thyme_oil.

TABLE 2 Selected constituents of thyme oil from *Thymus vulgaris* L. and *Thymus zygis* L. as defined by specifications, and batch to batch variation based on the analysis of 10 batches by gas chromatography with flame ionisation detector (GC–FID). The content of each constituent is expressed as the area percent of the corresponding chromatographic peak (% GC area), assuming the sum of chromatographic areas of all detected peaks as 100%.

Constituent			% GC area		
EU register name	**CAS No**	**FLAVIS No**	**Specification[(1)]**	**Mean**	**Range**
Thymol	89-83-8	04.006	35–60	49.6	42.6–54.8
p-Cymene (1-isopropyl-4-methylbenzene)	99-87-6	01.002	13–28	17.7	13.8–23.7
γ-Terpinene	99-85-4	01.020	4–13	8.6	7.2–11.0
Linalool	78-70-6	02.013	0.5–6.5	4.1	3.7–4.6

Abbreviations: CAS No, Chemical Abstracts Service number; EU, European Union; FLAVIS No, EU Flavour Information System numbers.
[1]Specification defined based on GC–FID analysis.

The EFSA Compendium of botanicals[21] reports as substances of potential concern for human and animal health the occurrence of 1,8-cineole (2.4%) and myrcene (2.1%) in the essential oil from the leaves of *T. vulgaris*. The EFSA Compendium also reports the occurrence of 1,8-cineole (≤ 20%), camphor (≤ 3.9%) and myrcene (≤ 2%–10%) in the essential oil from the aerial parts of *T. zygis*.

The applicant carried out an extensive literature search on the chemical composition of *T. vulgaris* and *T. zygis* and their botanical preparations and the possible presence of substances of concern.[22] Four cumulative databases (LIVIVO, OVID, PubMed and ToxInfo) were searched. The keywords used covered different aspects of safety, and the inclusion and exclusion criteria were provided by the applicant. The literature search (no time limits specified) identified 25 references investigating the composition of preparations from *T. vulgaris* and *T. zygis*. The results of the literature search confirmed the information in the EFSA Compendium. The presence of thujones and pulegone in *T. zygis* was reported in two websites,[23] but was not confirmed by any of the 25 references retrieved and was not reported in the EFSA Compendium.

3.3.1.1 | *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-chlorine pesticides, organo-phosphorous pesticides, aflatoxins (B1, B2, G1, G2) and ochratoxin A. However, no data were provided on the presence of these impurities.

3.3.2 | Shelf life

The typical shelf life of thyme 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.

3.3.3 | Conditions of use

Thyme oil is intended to be added to feed or water for drinking for all animal species without a withdrawal period. The maximum proposed use level is 100 mg thyme oil/kg complete feed. No use level has been proposed by the applicant for the use of the additive in water for drinking.

3.4 | Safety

No studies to support the safety for target animals, consumers and users were performed with the additive under assessment.

Sixty-two of the individual components of the essential oil, accounting on average for 98.1% of the GC peak areas, 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) superseded in 2008 by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and/or by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The flavouring compounds together with the EU Flavour Information System (FLAVIS) number, the chemical group as defined in Commission Regulation (EC) No 1565/2000,[25] and the corresponding

[21]Online version: https://www.efsa.europa.eu/en/data-report/compendium-botanicals, accessed on 15 May 2025.
[22]Technical dossier/Supplementary information July 2024/Literature search_Thyme_oil.
[23]https://www.vcf-online.nl/VcfHome.cfm (thujones); https://combodb.ecomole.com/report/3564?search=Thymus+zygis+ (pulegone).
[24]Technical dossier/Section II.
[25]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 1 80, 19.7.2000, p. 8.

EFSA opinion are listed in Table 3. 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 by EFSA for use in food and feed. *d*-Camphor is therefore included in Table 3.

TABLE 3 Flavouring components of thyme oil already assessed by EFSA and/or by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 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/JECFA 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
		Methyl 2-methylbutyrate[1]	09.438	
03	α, ß-Unsaturated (alkene or alkyne) straight-chain and branched-chain aliphatic primary alcohols/aldehydes/acids, acetals and esters	Geraniol	02.012	2016a
		(Z)-Nerol	02.058	
		Neral	05.170	
		trans-3,7-Dimethylocta-2,6-dienal (geranial)	05.188	
		Geranyl butyrate	09.048	
		Geranyl propionate	09.128	
		Neryl isovalerate[1]	09.471	WHO (1999) (JECFA)
04	Non-conjugated and accumulated unsaturated straight-chain and branched-chain aliphatic primary alcohols, aldehydes, acids, acetals and esters	Citronellol	02.011	2016b
		Hex-3(*cis*)-en-1-ol	02.056	
05	Saturated and unsaturated aliphatic secondary alcohols, ketones and esters with esters containing secondary alcohols	Octan-3-ol	02.098	2015a
		6-Methylhept-5-en-2-one	07.015	2015a, 2021a
		Octan-3-one	07.062	2015a, 2023b
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
		2-(4-Methylphenyl)propan-2-ol	02.042	
		4-Terpinenol	02.072	
		1-Terpinenol[1]	02.096	WHO (2000) (JECFA)
		β-Terpineol[1]	02.097	
07	Primary alicyclic saturated and unsaturated alcohols/aldehydes/acids/acetals/esters with esters containing alicyclic alcohols	*(1R,2R,5S)* 5-Isopropenyl-2-methylcyclopentane carboxaldehyde	05.123	2008a, AFC
08	Secondary alicyclic saturated and unsaturated alcohols, ketones, ketals and esters with ketals containing alicyclic alcohols or ketones and esters containing secondary alicyclic alcohols	*d,l*-Borneol	02.016	2016c, 2023c
		d,l-Isoborneol	02.059	
		d-Camphor[2]	07.215	
		d,l-Bornyl acetate	09.017	
		Fenchyl alcohol	02.038	2016c
		d,l-Bornyl formate[1]	09.082	2014a, CEF
		Pin-2-en-4-one[1,3] (verbenone)	07.196	2011a, CEF 2012, CEF
10	Secondary aliphatic saturated or unsaturated alcohols, ketones, ketals and esters with a second secondary or tertiary oxygenated functional group	4-Hydroxy-4-methylpentan-2-one[1]	07.165	2011b, CEF
13	Furanones and tetrahydrofurfuryl derivatives	Linalool oxide[4]	13.140	2012b
14	Furfuryl and furan derivatives	Furfural	13.018	2016d
16	Aliphatic and alicyclic ethers	1,8-Cineole	03.001	2012c, 2021b
18	Allylhydroxybenzenes	Eugenol	04.003	2011

TABLE 3 (Continued)

CG	Chemical group	Product (EU register name)	FLAVIS no	EFSA/JECFA opinion,* year
23	Benzyl alcohols, aldehydes, acids, esters and acetals	4-Isopropylbenzyl alcohol	02.039	2012d
		4-Isopropylbenzaldehyde	05.022	
		Methyl benzoate	09.725	
25	Phenol derivatives containing ring-alkyl, ring-alkoxy and side-chains with an oxygenated functional group	Thymol	04.006	2012e, 2023c
		Carvacrol	04.031	
26	Aromatic ethers including anisole derivatives	1-Isopropyl-2-methoxy-4-methylbenzene (thymyl methyl ether)	04.043	2012f
		Carvacryl methyl ether[1] (4-isopropyl-2-methoxy-1-methylbenzene)	04.059	2008b, AFC
		Carvacryl acetate[1] (5-isopropyl-2-methyl phenyl acetate)	09.337	2011c, CEF
		2-Isopropyl-5-methylphenyl acetate (thymyl acetate, thymol acetate)	09.253	
31	Aliphatic and aromatic hydrocarbons and acetals containing saturated aldehydes	1-Isopropyl-4-methylbenzene (*p*-cymene)	01.002	2015b
		1-Isopropenyl-4-methylbenzene	01.010	
		d-Limonene	01.045	
		Terpinolene	01.005	2015b, 2023c
		α-Phellandrene	01.006	
		α-Terpinene	01.019	
		γ-Terpinene	01.020	
		Pin-2(10)-ene (β-pinene)	01.003	2016e
		Pin-2(3)-ene (α-pinene)	01.004	
		β-Caryophyllene	01.007	
		Myrcene	01.008	
		Camphene	01.009	
		δ-3-Carene	01.029	
		3,7,10-Humulatriene[1,5]	01.043	2011d, CEF
		α-Muurolene[1,5]	01.052	
		β-Phellandrene[1,5]	01.055	
		1,1,7-trimethyltricyclo[2.2.1.0.(2.6)] heptane (tricyclene)[1,5]	01.060	
		Limonene[1]	01.001	2015a, CEF
		β-Bisabolene[1]	01.028	
		cis-3,7-Dimethyl-1,3,6-octatriene cis-β-Ocimene[1]	01.064	
32	Epoxides	β-Caryophyllene epoxide[1]	16.043	2014b, CEF

*FEEDAP opinion unless otherwise indicated.

[1]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.

[2]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, 2008c) and in feed (EFSA FEEDAP Panel, 2016c).

[3]EFSA evaluated a racemate, a mixture of (+/–)-verbenone (EFSA CEF Panel, 2012).

[4]Linalool oxide [13.140]: A mixture of *cis*- and *trans*-linalool oxide (5-ring) was evaluated [13.140] (EFSA FEEDAP Panel, 2012d).

[5]Evaluated applying the 'Procedure' described in the Guidance on the data required for the risk assessment of flavourings to be used in or on food (EFSA CEF Panel, 2010). No longer authorised for use as flavours in food, as the additional toxicity data requested (EFSA CEF Panel, 2011c) were not submitted and the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015a).

Camphor is present in the additive as a mixture of enantiomers (*d,l*-camphor, the ratio between *d*- and *l*-stereoisomers is not given) and accounts on average for 0.6% of the GC area.

Four compounds listed in Table 3, namely 1,3,7,10-humulatriene [01.043], α-muurolene [01.052], β-phellandrene [01.055] and tricyclene [01.060], have been evaluated in Flavouring Group Evaluations 25 Revision 2 by applying the procedure described in the Guidance on the data required for the risk assessment of flavourings to be used in or on foods (EFSA CEF Panel, 2010). For these compounds, for which there is no concern for genotoxicity, EFSA requested additional sub-chronic toxicity data (EFSA CEF Panel, 2011c). In the absence of these data, the CEF Panel was unable to complete its assessment (EFSA CEF Panel, 2015a). As a result, these compounds are no longer authorised for use as flavours in food. For these compounds, in the absence of toxicity data, the FEEDAP Panel applies the threshold of toxicological concern (TTC) approach or

read-across from structurally related substances, as recommended in the Guidance document on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee, 2019).

The remaining 58 components of thyme oil listed in Table 3, accounting on average about 97.6% of the GC area, are considered safe for use as flavourings. They are currently authorised for use in food[26] without limitations and for use in feed[27] at individual use levels higher than those resulting from the intended use of the essential oil in feed.

The major components thymol [04.006] and carvacrol [04.031], and other components belonging to CG 8, *d,l*-borneol [02.016] and *d*-camphor [07.147] were included in tolerance studies made with the mixture of flavourings referred to as 'Herbal' (EFSA FEEDAP Panel, 2023c). Linalool [02.013] and octan-3-one [07.062] were similarly tested in mixtures of flavourings named 'TuttiFrutti' and 'MilkyVanilla', respectively (EFSA FEEDAP Panel, 2020, 2023b). Based on these studies, the FEEDAP Panel concluded that thymol [04.006] and carvacrol [04.031] are safe at 125 mg/kg complete feed for all animal species, *d,l*-borneol [02.016] at 15 mg/kg, *d*-camphor [07.147] at 5 mg/kg, linalool [02.013] at 30 mg/kg and octan-3-one [07.062] at 10 mg/kg. The FEEDAP Panel considered that the conclusions reached for *d*-camphor [07.147] can be extrapolated to the mixture of isomers of camphor. By applying read-across, the FEEDAP Panel also concluded that *d,l*-bornyl acetate [09.017] and *d,l*-isoborneol [02.059] are safe for all animal species at 5 mg/kg complete feed (EFSA FEEDAP Panel, 2023c), and that octan-3-ol [02.098] is safe at 10 mg/kg complete feed (EFSA FEEDAP Panel, 2023b). In the current assessment, the conclusions reached for thymol and carvacrol are extrapolated to the esters, thymyl acetate and carvacryl acetate.

Twenty-seven volatile compounds have not been previously assessed for use as flavourings. The FEEDAP Panel notes that 20 of them[28] accounting for about 1.2% of the GC area are aliphatic monoterpenes or sesquiterpenes structurally related to flavourings already assessed in CG 6, CG 8 and CG 31 and a similar metabolic and toxicological profile is expected. Because of their lipophilic nature, they are expected to be rapidly absorbed from the gastro-intestinal tract, oxidised to polar oxygenated metabolites, conjugated and excreted, and not to accumulate in animal tissues and products (EFSA FEEDAP Panel, 2012a, 2015b, 2016c, 2016d). Humulene epoxide II is structurally related to β-caryophyllene epoxide in CG 32 and read-across is applied (EFSA CEF Panel, 2014b).

Six compounds (4-terpinenyl acetate, spathulenol, 2-(3-methyl-2-cyclopenten-1-yl)-2-methylpropionaldehyde, *trans*-sabinol, isothujol and 5-methyl-2-propylphenol) have not been previously assessed or are not structurally related to flavourings previously assessed. The genotoxic potential of the six compounds was predicted using the Organisation for Economic Co-operation and Development (OECD) QSAR Toolbox.[29] No alerts were identified for in vitro mutagenicity, genotoxic and non-genotoxic carcinogenicity, or other toxicity endpoints for spathulenol or isothujol. For the other components, structural alerts were due to the presence of an ester group for 4-terpinenyl acetate, an aldehyde group for 2-(3-methyl-2-cyclopenten-1-yl)-2-methylpropionaldehyde, a vinyl/allyl alcohol group for *trans*-sabinol and of a phenol group for 5-methyl-2-propylphenol. In these cases, predictions of mutagenicity by Ames test (with and without S9 mix) were made by 'read-across' analyses of data available for substances similar to the target compounds (i.e. analogues obtained by categorisation). Categories were defined using general mechanistic and endpoint profilers as well as empirical profilers. Sub-categorisation was performed 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 by the FEEDAP Panel.

3.4.1 | Safety for the target species

Tolerance studies in the target species and/or toxicological studies in laboratory animals with the essential oil under assessment were not submitted. In the absence of these data, the approach to the safety assessment of a mixture whose individual components are known is based on the safety assessment of each individual component (component-based approach). This approach requires that the mixture is sufficiently characterised and that the individual components can be grouped into assessment groups, based on structural and metabolic similarity. The combined toxicity can be predicted using the dose addition assumption within an assessment group, taking into account the relative toxic potency of each component (EFSA Scientific Committee, 2019).

As the additive under assessment is a fully defined mixture (the identified components represent > 99% of the GC area, see Section 3.3.1), the FEEDAP Panel applied a component-based approach to assess the safety for target species of the essential oil.

The oil under assessment contains thymol (up to 60% by specification), carvacrol and other components belonging to CG 8 (*d,l*-borneol, *d,l*-isoborneol, *d,l*-bornyl acetate, *d,l*-isobornyl acetate, camphor and fenchone), which are assessed separately from the other components of the oil, based on the results of tolerance trials with the mixture of flavourings

[26]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.

[27]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.

[28]*trans*-sabinene hydrate, 3,7-dimethylocta-1,5,7-trien-3-ol, γ-terpineol (CG 6); *cis*-dihydrocarvone, fenchone (CG 8); *trans*-3,7-dimethyl-1,3,6-octatriene, *m*-cymene, calamenene, α-thujene, α–copaene, aromadendrene, alloaramadendrene, isocadinene, γ-muurolene, viridiflorene, γ-cadinene, (+)-δ-cadinene, 2,4-thujadiene, β-gurjenene, β-cadinene (CG 31).

[29]Technical dossier/Supplementary information July 2024/Annex_VII_SIn_reply_Thyme_oil_QSAR.

'Herbal' (EFSA FEEDAP Panel, 2023b). Similarly, linalool, octan-3-one and octan-3-ol are assessed based on the results of the tolerance studies with the mixtures of flavourings 'TuttiFrutti' and 'MilkyVanilla' (EFSA FEEDAP Panel, 2020, 2023b). The remaining identified components are assessed using the component-based approach.

3.4.1.1 | *Components tested in tolerance trials with mixtures of flavourings*

Thymol and carvacrol and corresponding esters

At the proposed use level of 100 mg thyme oil/kg complete feed, the concentration of thymol [04.005] would be up to 60 mg/kg (considering the maximum concentration indicated in the specifications), that of carvacrol [04.031] up to 5.27 mg/kg complete feed, and the concentrations of thymyl acetate and carvacryl acetate up to 0.06 and 0.04 mg/kg complete feed, respectively. Since thymol and carvacrol are considered safe for all animal species at 125 mg/kg complete feed based on the results of tolerance trials with the mixture of flavourings 'Herbal' (EFSA FEEDAP Panel, 2023c), the FEEDAP Panel concludes that, with regards to the presence of thymol and carvacrol and their acetates, the use of thyme oil is safe at a maximum proposed use levels in complete feed for all animal species.

Other components tested in tolerance trials with a mixture of flavourings

The highest concentration in feed of octan-3-one [07.062] and octan-3-ol [02.098] resulting from the use of the additive at the maximum proposed use level of 100 mg thyme oil/kg complete feed would be 0.12 mg/kg complete feed.[30] This concentration is below the safe level of 10 mg/kg complete feed experimentally established for octan-3-one in tolerance trials with the mixture of flavourings 'MilkyVanilla' and extrapolated to octan-3-ol by applying read-across (EFSA FEEDAP Panel, 2023b).

For linalool [02.013], the highest concentration in feed resulting from the use of the additive at the maximum proposed use level of 100 mg thyme oil/kg complete feed would be 6.5 mg/kg complete feed.[31] This is below the value of 30 mg/kg complete feed established by the tolerance trials with the 'TuttiFrutti' mixture as safe for all animal species (EFSA FEEDAP Panel, 2020).

When considering the highest analysed concentrations in thyme oil, the four (iso)bornyl derivatives (*d,l*-borneol [02.016], *d,l*-isoborneol [02.059], *d,l*-bornyl acetate [09.017], *d,l*-bornyl formate [09.082]) account together for up to 3.31% of the GC area. The highest feed concentration for the sum of these derivatives resulting from the use of the thyme oil at the proposed use level of 100 mg thyme oil/kg complete feed would be 3.31 mg/kg complete feed.[32] This concentration is below the safe level of 15 mg/kg complete feed experimentally established for *d,l*-borneol in tolerance trials with the mixture of flavourings 'Herbal' and below the safe level of 5 mg/kg established for the other (iso)bornyl derivatives by applying read-across from *d,l*-isobornyl acetate (EFSA FEEDAP Panel, 2023c).

The highest concentrations of camphor and fenchone resulting from the use of the additive at the proposed use level of 100 mg thyme oil/kg complete feed would be up to 0.66 mg/kg up to 0.10 mg/kg, respectively.[33] These concentrations and their sum are below the safe level of 5 mg/kg established in tolerance trials for *d*-camphor and extrapolated to the isomeric mixtures of camphor and fenchone by applying read-across (EFSA FEEDAP Panel, 2023c).

3.4.1.2 | *Components other than those tested in tolerance trials*

Based on considerations related to structural and metabolic similarities, the remaining components were allocated to 16 assessment groups, corresponding to the chemical groups (CGs) 1, 3, 4, 6, 7, 8, 10, 13, 14, 16, 18, 23, 25, 26, 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, 2015b). The allocation of the components to the (sub-)assessment groups is shown in Table 4 and in the corresponding footnote.

For hazard characterisation, each component of an assessment group was first assigned to the structural class according to Cramer classification using Toxtree (version 3.1.0, May 2018[34]). For some components in the assessment group, toxicological data were available to identify no observed adverse effect levels (NOAEL). 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.

[30]Calculated considering the maximum proposed use level of 100 mg/kg complete feed and the highest analysed concentrations of octan-3-one (0.10%) and octan-3-ol (0.02%) in the 14 batches.

[31]Calculated considering the maximum proposed use level of 100 mg/kg complete feed and the highest specification of linalool (6.5%).

[32]Calculated considering the maximum proposed use level of 100 mg/kg complete feed and the highest concentration of *d,l*-borneol (3.13%), *d,l*-bornyl acetate (0.08%), *d,l*-isoborneol (0.02%), *d,l*-bornyl formate (0.08%) in the 14 batches.

[33]Calculated considering the maximum proposed use level of 100 mg/kg complete feed and the highest concentration of camphor (0.66%) and fenchone (0.10%) in the 14 batches.

[34]Toxtree includes both the original Cramer rule base with the 33 structural rules (Cramer et al., 1978) and an extended rule base with five additional rules which were introduced to overcome misclassification (in Class I or Class II) of several substances with low NOAELs. https://toxtree.sourceforge.net/.

Sub-chronic studies from which NOAEL values could be identified, were available for the following compounds: 120 mg/kg bw per day for several compounds in CG 1 (EFSA FEEDAP Panel, 2013), 345 mg/kg bw per day for the representative compound citral [05.020], a mixture of neral and geranial, in CG 3 (EFSA FEEDAP Panel, 2016a), 50 mg/kg bw per day for citronellol [02.011] and 127 mg/kg bw per day for hex-3(*cis*)-en-1-ol [02.056] in CG 4 (EFSA FEEDAP Panel, 2016b), 50 mg/kg bw per day for 6-methylhept-5-en-2-one [07.015] in CG 5 (EFSA FEEDAP Panel, 2021a), 250 mg/kg bw per day for terpineol [02.230][35] in CG 6 (EFSA FEEDAP Panel, 2012a), 54 mg/kg bw per day for furfural [13.018] in CG 14 (EFSA FEEDAP Panel, 2016d), 100 mg/kg bw per day for 1,8-cineole [03.001] in CG 16 (EFSA FEEDAP Panel, 2021b), 300 mg/kg bw per day for eugenol [04.003] in CG 18 (EFSA FEEDAP Panel, 2011), 44 mg/kg bw per day for myrcene [01.008], 154 mg/kg bw per day for *p*-cymene [01.002] and 222 mg/kg bw per day for β-caryophyllene [01.007] in CG 31 (EFSA FEEDAP Panel, 2015b, 2016e), and 109 mg/kg bw per day for β-caryophyllene epoxide [16.043] in CG 32 (EFSA CEF Panel, 2014b). For α-terpinene [01.019], the FEEDAP Panel identified a NOAEL of 60 mg/kg body weight (bw) per day for maternal toxicity from a teratogenicity study in female Wistar rat based on a reduced body weight gain observed at higher doses. The NOAEL of 60 mg/kg bw per day was divided by a factor of 2 to take account of the nature of the study (see Araujo et al., 1996; ECHA, 2018). In addition, for benzyl alcohol [02.020] the EFSA Panel on Food Additives and Flavourings (FAF) 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 carcinogenicity study in rats (EFSA FAF Panel, 2019).

For CG 1, a group NOAEL of 120 mg/kg per day was identified from the toxicological data available for several compounds, which is applied to hexan-1-ol [02.005] in the current assessment.

In CG 3, the NOAEL of 345 mg/kg bw per day for citral [05.020] was applied using read-across to geraniol [02.012], *(Z)*-nerol [02.058], neral [05.170], geranial [05.188], geranyl propionate [09.128] and neryl isovalerate [09.471].

In CG 6, a NOAEL of 250 mg/kg bw per day was identified for terpineol [02.230] and divided by a factor of 2 to take account of the nature of the study (EFSA FEEDAP Panel, 2012a). The resulting value of 125 mg/kg bw per day was used as the reference point for terpinyl derivatives, i.e. 4-terpinenol [02.072], α-terpineol [02.014], γ-terpineol, β-terpineol [02.097], 1-terpinenol [02.096] and 4-terpinenyl acetate.

In CG 8, the benchmark dose lower confidence limit for a benchmark response of 10% ($BMDL_{10}$) of 60 mg/kg bw per day for *d*-carvone (EFSA Scientific Committee, 2014) was applied to the structurally related ketone verbenone [07.196].

Read-across was applied using the NOAEL of 400 mg/kg bw per day for benzyl alcohol [02.010] to extrapolate to 4-isoproypylbenzyl alcohol [02.039], 4-isoproypylbenzaldehyde [05.022] and methyl benzoate [09.725] in CG 23.

For CG 25, a group NOAEL of 36 mg/kg per day was identified from the toxicological data available for several compounds (EFSA FEEDAP Panel, 2012e). In the current assessment, this NOAEL was applied to carvacryl methyl ether [04.049] and thymyl methyl ether [04.043] in CG 26.

Since a compound-specific NOAEL has been identified for α-terpinene [01.019], which is lower than that of *d*-limonene [01.045], the representative compound in CG 31, III, the FEEDAP Panel considered the need to review the read-across applied within this group. The assessment group 'cyclohexene derivatives' includes compounds characterised by the presence of at least two double bonds, which can be either isolated (as in *d*-limonene) or conjugated (as in α-terpinene). For the two subgroups of compounds, a refinement in read-across is applied as follow: the NOAEL of 250 mg/kg bw per day for *d*-limonene is applied to the compounds with isolated double bonds and the NOAEL of 60 mg/kg bw per day for α-terpinene to the compounds with conjugated double bonds.

The NOAELs of 44, 250 and 222 mg/kg bw per day for the representative compounds of CG 31, myrcene [01.008], *d*-limonene [01.045] and β-caryophyllene [01.007] were applied, respectively, using read-across to the compounds within sub-assessment groups II (*cis*-3,7-dimethyl-1,3,6-octatriene [01.064] and *trans*-3,7-dimethyl-1,3,6-octatriene), III (γ-terpinene [01.020], terpinolene [01.005], β-phellandrene [01.055] and β-bisabolene), V (α-pinene [01.004], α-thujene, camphene [01.009], β-pinene [01.003], (+)-δ-cadinene, δ-3-carene [01.029], aromadendrene, tricyclene [01.060], viridiflorene, γ-cadinene, α-muurolene [01.052], γ-muurolene and β-cadinene),[36] respectively (EFSA CEF Panel, 2015a, 2015b). In the current assessment, the NOAEL of 60 mg/kg bw per day identified for α-terpinene [01.019] and divided by a factor of 2 to take account of the nature of the study, is applied to α-phellandrene [01.006].

The NOAEL of 222 mg/kg bw per day for β-caryophyllene [01.007] was also applied to *trans*-sabinene hydrate and spathulenol in CG 6, *trans*-sabinol in CG 8 and 3,7,10-humulatriene [01.043] in CG 31,VI.[37] For spathulenol, the NOAEL of β-caryophyllene [01.007] was divided by a factor of 2 to take account of the uncertainty in read-across due to the presence of an additional cyclopropane ring. Similarly for 3,7,10-humulatriene, the NOAEL of β-caryophyllene was divided by a factor of 2 to take account of the uncertainty in read-across due to differences in the structure (extrapolation from a tricyclic to a macrocyclic non-aromatic compound) (EFSA FEEDAP Panel, 2023).

For the remaining compounds,[38] toxicity studies performed with the compounds under assessment and read-across was not possible. Therefore, the TTC approach was applied (EFSA FEEDAP Panel, 2017b; EFSA Scientific Committee, 2019).

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

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

[37]Grouping the components *trans*-sabinene hydrate, spathulenol (CG 6), *trans*-sabinol (CG 8) and 3,7,10-humulatriene [01.043] (CG 31, VI) with β-caryophyllene [01.007] and the other components assessed based on the same NOAEL of 222 mg/kg bw per day in CG 31,V had no impact on the outcome of the assessment (MOET 122).

[38]Methyl 2-methylbutyrate (CG 1); 2-(4-methylphenyl)propan-2-ol, (CG 6); 2-(3-methyl-2-cyclopenten-1-yl)-2-methylpropionaldehyde and *(1R,2R,5S)*-5-isopropenyl-2-methylcyclopentanecarboxaldehyde (CG 7); fenchyl alcohol and isothujol (CG 8); 4-hydroxy-4-methylpentan-2-one (CG 10); linalool oxide (CG 13); 5-methyl-2-propylphenol (CG 25); calamenene (CG 31, IVe); isocadinene, β-gurjenene and 2,4-thujadiene (CG 31,V).

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 each component in the assessment group, exposure in target animals (expressed as mg/kg bw per day) was estimated considering the maximum proposed use level of 100 mg thyme oil/kg complete feed, the percentage of the component in the oil and the default values for body weight and feed intake according to the guidance on the safety of feed additives for target species (EFSA FEEDAP Panel, 2017b). For those compounds covered by specifications (thymol, *p*-cymene, γ-terpinene and linalool, see Table 2), the indicated maximum specified concentration is used for the calculation of exposure. For the other components the highest analysed concentration in the additive is used.

For risk characterisation, the margin of exposure (MOE) was calculated for each component as the ratio between the reference point and the exposure. For an assessment group, (i) when a group reference point is available, a group MOE was calculated for the combined intake; (ii) when different reference points are available for the components, the combined (total) margin of exposure (MOET) was calculated as the reciprocal of the sum of the reciprocals of the MOE for the individual substances (EFSA Scientific Committee, 2019). A MOE(T) > 100 allowed for interspecies- and intra-individual variability. The compounds resulting individually in an MOE > 50,000 were not further considered in the assessment group as their contribution to the MOE(T) is negligible. They are listed in the footnote.[39]

The approach to the safety assessment of thyme oil is shown in Table 4 for chickens for fattening, which is the species with the highest ratio of feed intake/body weight and represents the worst-case scenario among the target species.

TABLE 4 Compositional data, intake values (calculated for chickens for fattening at 100 mg/kg complete feed), reference points and margin of exposure (MOE) for the individual components of thyme 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 concentration in the oil**	**Highest concentration in feed**	**Intake[1]**	**Cramer Class[2]**	**NOAEL[3]**	**MOE[4]**	**MOET[5]**
Constituent	–	%	mg/kg	mg/kg bw per day	–	mg/kg bw per day	–	–
CG 1								
Methyl 2-methylbutyrate	09.483	0.01	0.009	0.0008	I	*3*	3713	
CG 3								
Geranial	05.188	0.11	0.110	0.0099	(I)	345	34,937	
CG 4								
Citronellol	02.011	0.02	0.019	0.0017	(I)	**50**	29,314	
CG 5								
6-Methylhept-5-en-2-one	07.015	0.01	0.014	0.0012	(I)	**50**	40,753	
CG 6								
4-Terpinenol	02.072	1.68	1.680	0.1508	(I)	125[6]	829	
α-Terpineol	02.014	0.80	0.799	0.0717	(I)	125[6]	1743	
trans-Sabinene hydrate	–	0.32	0.323	0.0290	(I)	222	7656	
γ-Terpineol	–	0.25	0.254	0.0228	(I)	125[6]	5482	
Spathulenol	–	0.11	0.109	0.0098	(I)	111[7]	11,344	
3,7-Dimethylocta-1,5,7-trien-3-ol	–	0.09	0.090	0.0081	(I)	44	5446	
2-(4-Methylphenyl)propan-2-ol	02.042	0.09	0.092	0.0083	I	*3*	363	
MOET CG 06								**195**
CG 7								
2-(3-Methyl-2-cyclopenten-1-yl)-2-methylpropionaldehyde	–	0.11	0.112	0.0101	I	*3*	298	

(Continues)

[39]Compounds included in the assessment groups but not reported in the table: hexan-1-ol (CG 1); geraniol, geranyl butyrate, neral, *(Z)*-nerol, geranyl propionate and neryl isovalerate (CG 3); hex-3*(cis)*-en-1-ol (CG 4); β-terpineol, 4-terpinenyl acetate and 1-terpinenol (CG 6); *trans*-sabinol (CG 8); furfural (CG 14); eugenol (CG 18); 4-isopropylbenzaldehyde, methyl benzoate and 4-isopropylbenzyl alcohol (CG 23); *cis*-3,7-dimethyl-1,3,6-octatriene (*cis*-β-ocimene) (CG 31, II); m-cymene (CG 31, IVe); α-muurulene, γ-muurolene, α-copaene and β-cadinene (CG 31, V); humulene oxide (CG 32).

TABLE 4 (Continued)

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS No**	**Highest concentration in the oil**	**Highest concentration in feed**	**Intake[1]**	**Cramer Class[2]**	**NOAEL[3]**	**MOE[4]**	**MOET[5]**
(1R,2R,5S) 5-Isopropenyl-2-methylcyclopentanecarboxaldehyde	–	0.10	0.102	0.0102	I	*3*	328	
Group MOE CG 7							**156**	
CG 8								
Isothujol	–	0.15	0.150	0.0135	I	*3*	223	
Fenchyl alcohol	02.038	0.05	0.050	0.0045	I	*3*	668	
cis-Dihydrocarvone	–	0.05	0.050	0.0045	(II)	60	13,367	
Verbenone	07.196	0.02	0.021	0.0019	(II)	60	31,826	
Carvone	07.012	0.02	0.019	0.0017	(II)	60	35,177	
MOET CG 08								**163**
CG 10								
4-Hydroxy-4-methylpentan-2-one	07.165	0.03	0.030	0.0027	I	*3*	1114	
CG 13								
Linalool oxide	13.140	0.07	0.076	0.0068	II	*0.91*	133	
Linalool oxide (5-ring)	–	0.03	0.039	0.0035	II	*0.91*	257	
Group MOE CG 13							**88**	
CG 16								
1,8-Cineole	03.001	0.20	0.196	0.0176	(II)	**100**	5677	
CG 25								
5-Methyl-2-propylphenol	–	0.16	0.158	0.0142	I	*3*	212	
CG 26								
Carvacryl methyl ether	04.059	0.45	0.450	0.0404	(I)	36	891	
Thymyl methyl ether	04.043	0.21	0.206	0.0206	(I)	36	1947	
Group MOE CG 26							**611**	
CG 31, II (Acyclic alkanes)								
Myrcene	01.008	2.11	2.105	0.1890	(I)	**44**	233	
trans-β-Ocimene	–	0.07	0.070	0.0063	(I)	**44**	1947	
Group MOE CG 31, II							**225**	
CG 31, III (Cyclohexene hydrocarbons)								
γ-Terpinene	01.020	13.0	13.00	1.1670	(I)	250	214	
α-Terpinene	01.019	2.06	2.058	0.1848	(I)	**30**[8]	162	
d-Limonene	01.045	0.99	0.991	0.0890	(I)	**250**	2810	
α-Phellandrene	01.006	0.33	0.331	0.0297	(I)	30[8]	1010	
Terpinolene	01.005	0.33	0.330	0.0296	(I)	250	8439	
β-Phellandrene	01.055	0.32	0.320	0.0287	(I)	250	8703	
β-Bisabolene	01.028	0.10	0.100	0.0090	(I)	250	27,848	
MOET CG 31, III								**80**
CG 31, IVe (Benzene hydrocarbons, alkyl)								
p-Cymene	01.002	28.0	28.00	2.5136	(I)	**154**	61	
1-Isopropenyl-4-methylbenzene	01.010	0.07	0.122	0.0110	I	*3*	274	
Calamenene	–	0.02	0.027	0.0024	I	*3*	1253	
MOET CG 31, IVe								**48**
CG 31, V (Bi-, tricyclic, non-aromatic hydrocarbons)								
β-Caryophyllene	01.007	2.41	2.410	0.2164	(I)	**222**	1026	
α-Pinene	01.004	2.26	2.260	0.2029	(I)	222	1094	
α-Thujene	–	1.50	1.497	0.1344	(I)	222	1652	
Camphene	01.009	0.95	0.950	0.0853	(I)	222	2603	

TABLE 4 (Continued)

Essential oil composition			Exposure		Hazard characterisation		Risk characterisation	
Assessment group	**FLAVIS No**	**Highest concentration in the oil**	**Highest concentration in feed**	**Intake[1]**	**Cramer Class[2]**	**NOAEL[3]**	**MOE[4]**	**MOET[5]**
β-Pinene	01.003	0.82	0.820	0.0736	(I)	222	3016	
(+)-δ-Cadinene	–	0.15	0.151	0.0135	(I)	222	16,419	
δ-3-Carene	01.029	0.12	0.123	0.0110	(I)	222	20,105	
Aromadendrene	–	0.12	0.120	0.0108	(I)	222	20,608	
Tricyclene	01.060	0.10	0.100	0.0090	(I)	222	25,729	
Viridiflorene	–	0.10	0.104	0.0093	(I)	222	23,778	
Alloaromadendrene	–	0.08	0.080	0.0072	(I)	222	30,911	
γ-Cadinene	–	0.07	0.069	0.0062	(I)	222	35,728	
Isocadinene	–	0.03	0.026	0.0023	I	*3*	1281	
β-Gurjenene	–	0.02	0.009	0.0015	I	*3*	2063	
2,4-Thujadiene	–	0.01	0.005	0.0005	III	*0.15*	328	
MOET CG 31, V								**128**
CG 31, VI								
3,7,10-Humulatriene	01.043	0.21	0.206	0.0185	(I)	111[6]	6002	
CG 32								
β-Caryophyllene epoxide	16.043	0.38	0.384	0.0345	(III)	**109**	3162	

Abbreviations: MOE, margin of exposure; MOET, combined (total) MOE; NOAEL, no observed adverse effect level.

[1]Rounded intake values are shown in the Table.

[2]When a NOAEL value is available or read-across is applied, the allocation to the Cramer class is put into parentheses.

[3]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.

[4]The MOE for each component is calculated as the ratio of the reference point (no observed adverse effect level, NOAEL) to the intake (non-rounded values are use in the calculations). When a group reference point is available, a group MOE is calculated for the combined intake. Group MOE values are reported **in bold**.

[5]The combined margin of exposure (MOET) is calculated for each assessment group as the reciprocal of the sum of the reciprocals of the MOE for the individual substances. MOET values are reported **in bold**.

[6]A factor of 2 was applied to the NOAEL of 250 mg/kg bw per day for terpineol because of the short duration of the study.

[7]A factor of 2 was applied to the NOAEL of 222 mg/kg bw per day for β-caryophyllene because of the differences in the structures.

[8]A factor of 2 was applied to the NOAEL of 60 mg/kg bw per day for α-terpinene because of the nature of the study.

As shown in Table 4, for several assessment groups, the MOE(T) calculated for chickens for fattening at the maximum proposed use level of the additive of 100 mg/kg complete feed was < 100. The lowest MOET of 58 was calculated for CG 31, IVe. The MOET for CG 31, IVe compounds calculated for the other target species at 100 mg/kg complete feed are summarised in Table 5.

TABLE 5 Combined margin of exposure (MOET) for the assessment group CG 31, IVe calculated for the different target animal species/categories at the maximum proposed use level of 100 mg/kg complete feed and maximum safe use level in feed.

Animal species/category	Daily feed intake (g DM/kg bw)	Lowest MOET CG 31, IVe	Maximum safe use level (mg/kg complete feed)[1]
Chickens for fattening	79	48	48
Laying hens	53	72	72
Turkeys for fattening	59	64	64
Piglets	44	86	86
Pigs for fattening	37	102	–[2]
Sows	30	126	–[2]
Veal calves (milk replacer)	19	214	–[2]
Cattle for fattening	20	190	–[2]
Dairy cows	31	122	–[2]
Sheep/goats	20	190	–[2]
Horses	20	190	–[2]
Rabbits	50	76	76
Salmonids	18	211	–[2]

(Continues)

TABLE 5 (Continued)

Animal species/category	Daily feed intake (g DM/kg bw)	Lowest MOET CG 31, IVe	Maximum safe use level (mg/kg complete feed)[1]
Dogs	17	223	–[2]
Cats[3]	20	38	38
Ornamental fish	5	758	–[2]

Abbreviations: bw, body weight; DM, dry matter; MOET, combined (total) MOE.

[1]Complete feed containing 88% DM, milk replacer 94.5% DM.

[2]For the species for which the MOET is > 100, the maximum proposed use level of 100 mg/kg complete feed is considered safe.

[3]The MOET for cats is increased to 500 because of their reduced capacity of glucuronidation.

At the proposed use levels in complete feed, the MOET exceeds the value of 100 for pigs for fattening, sows, veal calves, cattle for fattening, dairy cows, sheep/goats, horses, salmonids, dogs and ornamental fish. For the other species the maximum safe use levels in feed were calculated to ensure a MOET ≥ 100. Because glucuronidation is an important metabolic reaction to facilitate the excretion of the components of the essential oil and considering that cats have an unusually low capacity for glucuronidation particularly for aromatic compounds (Court & Greenblatt, 1997; Lautz et al., 2021), the use of thyme oil as additive in cat feed needs a wider margin of exposure. A MOET of 500 is considered adequate. The maximum proposed use level of 100 mg/kg complete feed is safe for pigs for fattening, sows, veal calves, cattle for fattening, dairy cows, sheep/goats, horses, salmonids, dogs and ornamental fish. For the other species, the resulting maximum safe levels in feed are shown in Table 5.

3.4.1.3 | *Overall evaluation*

When considering the assessment of the individual components or groups of components of thyme oil, the maximum proposed use level of 100 mg/kg complete feed is safe for pigs for fattening, sows, veal calves, cattle for fattening, dairy cows, sheep/goats, horses, salmonids, dogs and ornamental fish. For chickens for fattening, laying hens, turkeys for fattening, piglets, rabbits and cats, the safe concentrations in feed were derived for the assessment group CG 31, IVe (see Table 5). These levels are extrapolated to physiologically related species. For the other species not considered, the calculated maximum safe level of 38 mg additive/kg complete feed is applied.

No specific use levels have been proposed by the applicant for the use of thyme oil in water for drinking. The FEEDAP Panel considers that the use of the additive in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed.

3.4.1.4 | *Conclusions on safety for the target species*

The FEEDAP Panel considers that the levels of thyme oil summarised in Table 6 are safe for the respective target species.

TABLE 6 Safe concentrations of thyme oil in complete feed (mg/kg) for all animal species and categories.

Animal categories	Safe concentration (mg/kg complete feed)[1]
Turkeys for fattening	64
Chickens for fattening, other poultry for fattening or reared for laying/reproduction and ornamental birds	48
Laying hens and other laying/reproductive birds	72
Pigs for fattening	100
Piglets and other porcine species for meat production or reared for reproduction	86
Sows and other porcine species for reproduction	100
Veal calves (milk replacer)	100
Sheep/goats	100
Cattle for fattening, other ruminants for fattening or reared for milk production/reproduction, cervids and camelids at the same physiological stage	100
Dairy cows and other ruminants, cervids and camelids for milk production or reproduction	100
Horses and other equids	100
Rabbits and other leporids	76
Salmonids and minor fin fish	100
Dogs	100
Cats	38
Ornamental fish	100
Other species	38

[1]Complete feed containing 88% dry matter, milk replacer 94.5% dry matter.

The FEEDAP Panel considers that the use of the additive in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed.

3.4.2 | Safety for the consumer

The leaves of *T. vulgaris* and *T. zygis* (thyme) and their oils are added to a wide range of food categories for flavouring purposes. Although individual consumption figures are not available, the Fenaroli's handbook of flavour ingredients (Burdock, 2009) cites intake values of 0.6483 mg/kg bw per day for thyme and 0.0031 mg/kg bw per day for thyme oil. The Fenaroli handbook also reports use levels in food and beverages in the range of 2.35 mg/kg up to 34 mg/kg for thyme oil.

Most of the individual constituents of the essential oil under assessment are currently authorised as food flavourings without limitations and have been already assessed for consumer safety when used as feed additives in animal production (see Table 3, Section 3.4).

No data on residues in products of animal origin were made available for any of the constituents of the essential oil. However, the Panel recognises that the constituents of thyme oil are expected to be extensively metabolised and excreted in the target species. For the major components, the data available for thymol, *p*-cymene, γ-terpinene, linalool and carvacrol indicate that they are absorbed, metabolised and rapidly excreted and are not expected to accumulate in animal tissues and products (EFSA FEEDAP Panel, 2012a, 2012e, 2015b). Consequently, relevant residues in food products are unlikely.

Considering the above and the reported human exposure due to the direct use of thyme and its preparations in food (Burdock, 2009), the FEEDAP Panel considers that the consumption of products from animals given thyme oil at the maximum use level proposed by the applicant would be unlikely to significantly increase human background exposure.

The use of thyme oil in animal nutrition under the proposed conditions of use is considered safe for human consumers of animal products.

3.4.3 | Safety for the user

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

A literature search related to the safety of preparations obtained from *T. vulgaris* and *T. zygis* for users did not retrieve any relevant publication.[40]

The applicant provided a safety data sheet[41] for thyme oil, which identified concerns for dermal and eye irritation and dermal and respiratory sensitisation.

The FEEDAP Panel concludes that thyme oil should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. Exposure of users by any route is considered a risk.

3.4.4 | Safety for the environment

T. vulgaris and *T. zygis* are species native to Europe where they are cultivated for culinary and ornamental purposes. Therefore, the use of thyme oil in animal feed under the proposed conditions of use is not expected to pose a risk to the environment.

3.5 | Efficacy

The leaves of thyme (*T. vulgaris* L. and *T. zygis* L.) and their oils are listed in Fenaroli's Handbook of Flavour Ingredients (Burdock, 2009) and by the Flavour and Extract Manufactures Association (FEMA) with the reference numbers 3063, 3064 and 3065.

Since the leaves of *T. vulgaris* and *T. zygis* and their preparations are recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary for thyme oil.

4 | CONCLUSIONS

The conclusions of the FEEDAP Panel on the safe levels of thyme oil in complete feed for all animal species are summarised as follows:

[40]Technical dossier/Supplementary information July2024/Literature search_Thyme oil.

[41]Technical dossier/Supplementary information July 2024/Annex VIII_SIn_reply_Thyme_oil_MSDS. Aspiration hazard (H304, Category 1), Hazard for skin corrosion/irritation (H314, Category 1B), Skin sensitisation (H317, Category 1), Reproductive toxicity (H361, Category 2), in accordance with the criteria outlined in Annex I of 1272/2008/EC (CLP/EU-GHS).

Animal categories	Safe concentration (mg/kg complete feed)[1]
Turkeys for fattening	64
Chickens for fattening, other poultry for fattening or reared for laying/reproduction and ornamental birds	48
Laying hens and other laying/reproductive birds	72
Pigs for fattening	86
Piglets and other porcine species for meat production or reared for reproduction	100
Sows and other porcine species for reproduction	100
Veal calves (milk replacer)	100
Sheep/goats	100
Cattle for fattening, other ruminants for fattening or reared for milk production/reproduction, cervids and camelids at the same physiological stage	100
Dairy cows and other ruminants, cervids and camelids for milk production or reproduction	100
Horses and other equines	100
Rabbits and other leporids	76
Salmonids and minor fin fish	100
Dogs	100
Cats	38
Ornamental fish	100
Other species	38

[1]Complete feed containing 88% dry matter, milk replacer 94.5% dry matter.

The FEEDAP Panel considers that the use of the additive in water for drinking is safe provided that the total daily intake of the additive does not exceed the daily amount that is considered safe when consumed via feed.

The use of thyme oil in animal feed under the proposed conditions of use is safe for the consumer and the environment.

Regarding user safety, the essential oil under assessment should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. Exposure of users by any route is considered a risk.

Since the leaves of *T. vulgaris* L. and *T. zygis* L. and their preparations are recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary.

5 | DOCUMENTATION PROVIDED TO EFSA/CHRONOLOGY

Date	Event
23/11/2010	Dossier received by EFSA. Botanically defined flavourings from Botanical Group 01 – Lamiales for all animal species and categories. Submitted by Feed Flavourings Authorisation Consortium European Economic Interest Grouping (FFAC EEIG)
03/01/2011	Reception mandate from the European Commission
06/01/2011	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. *Issues: analytical methods*
08/01/2013	Reception of supplementary information from the applicant - Scientific assessment remains suspended
26/02/2013	EFSA informed the applicant (EFSA ref. 7150727) that, in view of the workload, the evaluation of applications on feed flavourings would be re-organised by giving priority to the assessment of the chemically defined feed flavourings, as agreed with the European Commission
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
30/06/2021	EFSA informed the applicant that the evaluation process restarted
08/07/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation, safety for target species, safety for the consumer, safety for the user and environment*
28/09/2023	Partial withdrawal of the application for the following additive: Spanish majoram oil
08/07/2024	Reception of supplementary information from the applicant (partial dataset: thyme oil) - Scientific assessment remains suspended
08/07/2024	Partial withdrawal of the application for the following additives: lilac chastetree extract and savoury summer tincture
26/08/2024	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives. Partial report related to seven additives: Spanish sage oil, peppermint oil, thymus origanum oil, patchouli oil, clary sage oil, lavender oil and sage oil

Date	Event
16/12/2024	Partial withdrawal of the application for the following additives: devils claw extract (wb), balm leaves extract (sb), olive extract (sb)
18/06/2025	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives. Partial report related to 11 additives: cornmint oil, spearmint oil, thyme oil, rosemary oil, marjoram oil, rosemary tincture, basil tincture, lavender tincture, peppermint tincture, sage tincture and wild thyme tincture
26/06/2025	The application was split and a new EFSA-Q-2025-00403 was assigned to the preparation included in the present assessment Scientific assessment re-started for the preparation included in the present assessment
17/09/2025	Opinion adopted by the FEEDAP Panel on thyme oil (EFSA-Q-2025-00403). End of the Scientific assessment for the preparation included in the present assessment. The assessment of other preparations in BGD 01 is still ongoing
18/11/2025	Opinion readopted by the FEEEDAP Panel. End of the Scientific assessment for the additive included in the present assessment. The assessment of other additives in BGD 01 is still ongoing

ABBREVIATIONS

AFC	EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food
BDG	botanically defined group
BMD	benchmark dose
$BMDL_{10}$	benchmark dose lower confidence limit for a benchmark response of 10%
BW	body weight
CAS	Chemical Abstracts Service
CDG	chemically defined group
CEF	EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CG	chemical group
CLP	Classification, Labelling and Packaging
CoE	Council of Europe
DM	dry matter
ECHA	European Chemicals Agency
EMA	European Medicines Agency
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FFAC	Feed Flavourings authorisation Consortium of FEFANA (EU Association of Specialty Feed Ingredients and their Mixtures)
FGE	food group evaluation
FLAVIS	The EU Flavor Information System
FL-no	FLAVIS number
GC-FID	gas chromatography–flame ionisation detection
GC–MS	gas chromatography–mass spectrometry
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
MOE	margin of exposure
MOET	combined (total) margin of exposure
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PhEur	European Pharmacopoeia
QSAR	quantitative structure activity relationship
TTC	threshold of toxicological concern
WHO	World Health Organization

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REQUESTOR

European Commission

QUESTION NUMBER

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