

## SCIENTIFIC OPINION

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# Safety and efficacy of an essential oil of *Origanum vulgare* ssp. *hirtum* (Link) leetsw. for all poultry species

EFSA Panel on Additives and Products or Substances used in Animal Feed  
(EFSA FEEDAP Panel),

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### Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of an essential oil of *Origanum vulgare* ssp. *hirtum* (Link) leetsw. for all poultry species. The essential oil under assessment obtained [REDACTED] is specified to contain carvacrol [REDACTED] and thymol (7%). The remaining 30% of the composition remains uncharacterised. In the absence of these data, the FEEDAP Panel was unable to make a risk assessment of the additive for the target species, the consumer and the user. Use in animal production of the essential oil extracted from *O. vulgare* ssp. *hirtum* (Link) leetsw. is not expected to pose a risk for the environment. Since oregano and its extracts are universally recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary.

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## 1. Introduction

### 1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from Uncle Teds Organics Ltd<sup>2</sup> for re-evaluation of an essential oil from *Origanum vulgare* L. ssp. *hirtum*, when used as a feed additive for poultry (category: sensory additives; functional group: flavouring compounds).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) 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 9 March 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 the product oil of *O. vulgare* L. ssp. *hirtum*, when used under the proposed conditions of use (see Section 3.2.2).

### 1.2. Additional information

Oregano oil from *O. vulgare* 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).

The EFSA FEEDAP Panel issued an opinion on the safety and efficacy of *O. vulgare* L. ssp. *hirtum* var. Vulkan, when used as a feed additive for all animal species (EFSA FEEDAP Panel, 2017).

## 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<sup>3</sup> in support of the authorisation request for the use of oil of *O. vulgare* ssp. *hirtum* (Link) leetsw. as a feed additive.

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.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of oil of *O. vulgare* ssp. *hirtum* (Link) leetsw. in animal feed. The Executive Summary of the EURL report can be found in Annex A.<sup>4</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of an essential oil from *O. vulgare* ssp. *hirtum* (Link) leetsw. is in line with the principles laid down in Regulation (EC) No 429/2008<sup>5</sup> and the relevant guidance documents: Guidance on safety assessment of botanicals and

<sup>1</sup> 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.

<sup>2</sup> Uncle Teds Organics Ltd, Lane Head Farm, Roils Head Road Norton Tower, HX2 OSU, Halifax, Norton Tower.

<sup>3</sup> FEED dossier reference: FAD-2010-0381.

<sup>4</sup> The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/default/files/FiniRep-FAD-2010-0381.pdf>

<sup>5</sup> 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.

botanical preparations intended for use as ingredients in food supplements (EFSA, 2009), Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements (EFSA, 2012), Guidance for the preparation of dossiers for sensory additives (EFSA FEEDAP Panel, 2012a), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008), Guidance for the preparation of dossiers for additives already authorised for use in food (EFSA FEEDAP Panel, 2012b), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012c) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012d).

### 3. Assessment

This application covers an essential oil derived [REDACTED] from *O. vulgare* ssp. *hirtum* (Link) leetsw. when used as a sensory additive (functional group: flavouring compounds) in feed for poultry.

#### 3.1. Origin and extraction

*Origanum* is a genus of herbaceous plants belonging to the mint family (Lamiaceae), native to Europe, North Africa and temperate areas of Asia. The genus contains a number of species widely used for culinary purposes and as medicinal plants. The most commonly encountered are *O. vulgare*, known as 'oregano' in most European countries, and *O. majorana* (sweet marjoram). The related species *O. onites* (Pot marjoram or Turkish oregano) and *O. syriacum* (Syrian oregano) are similarly used as culinary herbs and a source of flavours. Cuban oregano also belongs to the mint family but from another genus (*Plectranthus ambonicus*), while Mexican oregano (*Lippia graveolens*) belongs to an entirely different plant family (Verbenaceae).

Five subspecies of *O. vulgare* are presently recognised of which the subspecies *viridulum*, *viride* and *hirtum* are the most commonly found in Europe. The essential oil from the subspecies *hirtum* is considered of particular quality and oils from this subspecies from different locations and varieties have been extensively analysed. Analysis has shown that within this subspecies, two main chemotypes can be recognised (carvacrol-rich or thymol-rich oils) together with intermediate types containing both isomers and other types in which the precursors, *p*-cymene and  $\gamma$ -terpinene, also are present in significant amounts (D'Antuono et al., 2000).

The essential oil of *O. vulgare* ssp. *hirtum* (Link) leetsw. is produced [REDACTED] of the plant. The major source is from Mediterranean areas especially Greece.

#### 3.2. Characterisation of the essential oil

The product under assessment is a clear, mobile yellowish to brown liquid with a characteristic odour. Based on information from the literature,<sup>6</sup> the essential oil is composed predominantly of carvacrol and to a lesser extent, *p*-cymene,  $\gamma$ -terpinene and thymol with varying percentages of other phenolic compounds.

The product specifications as proposed by the applicant are based on the main components of the essential oil: carvacrol [REDACTED] and thymol (7%).

Analysis of two recent batches showed concentrations of carvacrol and thymol of 67.3–67.7%, 2.92–2.63%, respectively. The content of thymol is below the proposed specification.

Analytical data on the full characterisation of the essential oil were not submitted, despite being requested. The applicant provided a table extracted from a publication (Konakchiev et al., 2004) that shows the typical composition of the essential oil described as originating from oregano. However, the data reported for 15 samples showed a high variability in the content of carvacrol (from 56.3% to 78.8%), *p*-cymene (from 3.5% to 17.8%),  $\gamma$ -terpinene (from 4.3% to 18.9%) and a lower content of thymol (from trace amounts to 0.3%) compared to the oil under assessment. Considering that carvacrol and thymol account for about 70% of the composition of the essential oil under assessment, the 30% of the composition remains uncharacterised.

No data on the possible microbiological or chemical contamination (heavy metals and arsenic, mycotoxins, pesticides, dioxins and dioxin-like polychlorinated biphenyls) were provided. The applicant claims that since the essential oil is produced [REDACTED], only volatile impurities are possible.

<sup>6</sup> Technical dossier/Section II/Section 2.1.3, pp. 2–3.

### 3.2.1. Stability and homogeneity

The additive is claimed to be stable in sealed containers at less than 25°C for 2 years. No data to confirm this statement were provided.

### 3.2.2. Conditions of use

The additive is intended for use in feed for all poultry species at a minimum concentration of 12.3 mg essential oil/kg complete feed and a maximum concentration of 18.4 mg essential oil/kg complete feed.

## 3.3. Safety for the target species, the consumer and the user

Tolerance studies and/or toxicological studies made with the essential oil under application were not submitted. In addition the additive was not sufficiently characterised to allow an assessment based on individual components.

No specific studies on absorption, distribution, metabolism and excretion with the oil under assessment and with the individual constituents were provided. No data on residues in products of animal origin were made available for any of the constituents of the essential oil.

No data on the safety for user were provided.

In the absence of these data, the FEEDAP Panel is unable to make a risk assessment of the additive for the target species, the consumer and the user.

### 3.3.1. Safety for the environment

*Origanum vulgare* is a native species to Europe where it is widely grown both for commercial and decorative purposes. Use of the essential oil under the proposed conditions of use in animal production is not expected to pose a risk for the terrestrial or fresh water environment.

## 3.4. Efficacy

Under the terms Regulation (EC) No 1334/2008 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'. Consequently, there is no specific EU authorisation for any *Origanum vulgare* extract when used to provide flavour in food. However, oregano and its preparations are listed in Fenaroli's Handbook of Flavour Ingredients and by the Flavour and Extract Manufacturers Association (FEMA) with the reference number 2828.

Since oregano and its extracts are universally recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary.

## 4. Conclusions

In the absence of data, the FEEDAP Panel is unable to make a risk assessment of the additive for the target species, the consumer and the user.

Use in animal production of the essential oil extracted from *O. vulgare* ssp. *hirtum* (Link) leetsw. is not expected to pose a risk for the environment.

Since oregano and its extracts are universally recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary.

## Documentation provided to EFSA

- 1) Oil of *Origanum vulgare* L. subsp. *Hirtum* for poultry. November 2010. Submitted by Uncle Teds Organics Ltd.
- 2) Oil of *Origanum vulgare* L. subsp. *Hirtum* for poultry. Supplementary information. October 2018. Submitted by Uncle Teds Organics Ltd.
- 3) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for Oregano oil (*Origanum vulgare*).
- 4) Comments from Member States.



## Chronology

Date	Event
10/11/2010	Dossier received by EFSA
13/02/2018	Reception mandate from the European Commission
07/03/2018	Application validated by EFSA – Start of the scientific assessment
03/04/2018	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. <i>Issues: characterisation, safety for target species, safety for the consumer and safety for the user</i>
08/06/2018	Comments received from Member States
31/10/2018	Reception of letter from the applicant informing EFSA that the supplementary information requested will not be submitted – Scientific assessment re-started
27/02/2019	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
28/02/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance for the preparation of dossiers for sensory additives. *EFSA Journal* 2012;10(1):2534, 26 pp. <https://doi.org/10.2903/j.efsa.2012.2534>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance for the preparation of dossiers for additives already authorised for use in food. *EFSA Journal* 2012;10(1):2538, 4 pp. <https://doi.org/10.2903/j.efsa.2012.2538>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Guidance for establishing the safety of additives for the consumer. *EFSA Journal* 2012;10(1):2537, 12 pp. <https://doi.org/10.2903/j.efsa.2012.2537>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012d. Guidance on studies concerning the safety of use of the additive for users/workers. *EFSA Journal* 2012;10(1):2539, 5 pp. <https://doi.org/10.2903/j.efsa.2012.2539>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Cocconcilli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Brantom P, Dusemund B, Van Beelen P, Westendorf J, Gregoretto L, Manini P and Chesson A, 2017. Scientific Opinion on the safety and efficacy of an essential oil from *Origanum vulgare* subsp. *hirtum* (Link) letsw. var. *Vulkan* when used as a sensory additive in feed for all animal species. *EFSA Journal* 2017;15(12):5095, 16 pp. <https://doi.org/10.2903/j.efsa.2017.5095>
- Konakchiev A, Genova E and Couladis M, 2004. Chemical composition of the essential oil of *Origanum vulgare* ssp. *hirtum* (Link) letswaart in Bulgaria. *Comptes Rendus de l'Académie Bulgare des Sciences*, 57, 49–52.

## Abbreviations

- EURL European Union Reference Laboratory  
 FEEDAP EFSA Panel on Additives and Products or Substances used in Animal Feed

## Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Oregano oil (*Origanum vulgare*)

In the current application authorisation is sought under Article 10(2) for the botanically defined *Oregano oil (Origanum vulgare)* under the category/functional group (2 b) 'sensory additives'/flavouring compounds', according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, the *feed additive* is sought to be used for poultry.

According to the Applicant, the phytochemical markers of the *feed additive* are *carvacrol* and *thymol* where the sum of the content of the two compounds is minimum 60% expressed as a sum of the relative peak areas in the chromatogram. Therefore the characterisation of this *feed additive* is compliant with the definition of *Oregano oil* given in the monograph of the European Pharmacopoeia (Ph. Eur. 01/2008:1880). The *feed additive* is intended to be used in feed with a proposed level ranging between 12.3 and 18.4 mg/kg of complete *feedingstuffs*.

For the determination of the phytochemical markers in the *feed additive* the EURL identified the international standard 'ISO 13171 – Essential oil of oregano' where, in accordance with 'ISO 11024:1998 Essential oils - General guidance on chromatographic profiles', a specific chromatographic profile derived from a GC-FID method is presented. The Applicant identified instead the *Oregano* monograph of the European Pharmacopoeia (Ph. Eur. 01/2008:1880) where a specific test, equivalent to the method described in ISO 13171, is described for the determination of the two phytochemical compounds of interest. The Applicant analysed some samples by demonstrating satisfactory results applying the method described in the above mentioned monograph.

Based on the experimental evidence the EURL recommends for official control for the determination of the two phytochemical markers (*carvacrol* and *thymol*) in the *feed additive* the GC-FID method as indicated in the 'European Pharmacopoeia monograph 01/2008:1880 for oregano' and equivalent to the international standard 'ISO 13171 – Essential oil of oregano'.

The Applicant did not provide experimental data or an analytical method for the determination of *Oregano oil* in *premixtures* and *feedingstuffs* as the unambiguous determination of the *feed additive* added to the matrices is not achievable experimentally. Therefore, the EURL cannot evaluate or recommend any method for official control for the determination of *Oregano oil* in *premixtures* and *feedingstuffs*.

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