

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/1248****of 19 July 2022****concerning the authorisation of essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. as a feed additive for certain animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC <sup>(2)</sup>.
- (2) Essential oil from *Origanum vulgare* was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. for all animal species.
- (4) The applicant requested the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 November 2019 <sup>(3)</sup> that, under the proposed conditions of use, essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. does not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. should be considered as an irritant to skin and eyes, and as a potential skin and respiratory sensitizer. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (6) The Authority also concluded, that essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. is recognised to flavour food and its function in feed would be essentially the same as that in food, therefore, no further demonstration of efficacy is considered necessary. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) The assessment of essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Ietsw. shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding stuffs (OJ L 270, 14.12.1970, p. 1).

<sup>(3)</sup> EFSA Journal 2019;17(12):5909.

- (8) The additive concerned contains some components such as carvacrol and thymol for which zootechnical effects have been demonstrated in certain additives already authorised. In order to prevent the use of doses of the additive which could potentially lead to such zootechnical effects, it is necessary to establish a maximum content as a condition of use of essential oil from *Origanum vulgare* ssp. *hirtum* (Link) Letsw. as a flavouring in feed.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Authorisation**

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*

**Transitional measures**

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 9 February 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing this substance as specified in the Annex which are produced and labelled before 9 August 2023 in accordance with the rules applicable before 9 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

*Article 3*

**Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 July 2022.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feeding stuff with a moisture content of 12 %			

**Category: Sensory additives. Functional group: Flavouring compounds**

2b317-e-o-i	-	Essential oil from <i>Origanum vulgare</i> ssp. <i>hirtum</i> (Link) Ietsw.	<p><i>Additive composition:</i> Essential oil from <i>Origanum vulgare</i> ssp. <i>hirtum</i> (Link) Ietsw.</p> <p><i>Characterisation of the active substance:</i> Essential oil from <i>Origanum vulgare</i> ssp. <i>hirtum</i> (Link) Ietsw. as defined by the Council of Europe <sup>(1)</sup>.</p> <p>Carvacrol: ≥ 75 % Thymol: ≤ 2,7 % γ-Terpinene: ≤ 3,8 % p-Cymene: ≤ 6,2 %</p> <p>CoE number: 317 CAS number: 336185-21-8 FEMA number: 2660</p> <p><i>Method of analysis</i> <sup>(2)</sup></p> <p>For the determination of carvacrol (phytochemical marker) in the feed additive: — gas chromatography coupled to flame ionisation detection (GC-FID) – ISO 13171.</p>	Chickens for fattening	-	-	22	<p>1. The additive shall be incorporated into feed in the form of a premixture.</p> <p>2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.</p> <p>3. The mixture of essential oil from <i>Origanum vulgare</i> L. subsp. <i>hirtum</i> (Link) Ietsw. with other authorised additives obtained from <i>Origanum vulgare</i> L. shall not be allowed in feeding stuffs.</p> <p>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protection.</p>	9.8.2032
				Laying hens	-	-	33		
				Turkeys for fattening	-	-	30		
				Piglets	-	-	40		
				Pigs for fattening	-	-	48		
				Sows	-	-	63		
				Dairy cows	-	-	57		
				Calves	-	-	100		
				Cattle for fattening, sheep, goats and horses	-	-	88		
				Rabbits	-	-	35		
				Dogs	-	-	106		
				Cats	-	-	18		
Salmonids	-	-	101						
Ornamental fish	-	-	150						

<sup>(1)</sup> Natural sources of flavourings – Report No 2 (2007).

<sup>(2)</sup> Details of the methods of analysis are available at the following address of the Reference Laboratory: [https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports\\_en](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)