

COMMISSION IMPLEMENTING REGULATION (EU) 2023/650**of 20 March 2023****concerning the authorisation of a preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and minor poultry species reared for breeding (holder of authorisation: Biomin GmbH)****(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 ⁽¹⁾, 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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol as a feed additive for all poultry species, to be classified in the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives'. As the preparation was already authorised for the same holder of authorisation by Commission Implementing Regulation (EU) 2020/996 ⁽²⁾ as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species reared for laying, the request for authorisation in accordance with Article 4 of Regulation (EC) No 1831/2003 is considered only for the species not covered by the previous authorisation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 June 2022 ⁽³⁾ that, under the proposed conditions of use, the preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol does not have an adverse effect on consumer safety or the environment and that the aforementioned preparation is safe for poultry species for fattening or reared for laying or breeding. In the absence of adequate data, it could not conclude on the safety of the said preparation for laying or breeding birds. The Authority also concluded that an exposure of users by inhalation is unlikely and that the conclusions of the previous opinion regarding the safety for the users apply also to the present assessment. In the context of the previous opinion on this additive, adopted on 15 May 2019 ⁽⁴⁾, the safety data sheet required by Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽⁵⁾ described skin irritation, eye irritation and allergic skin reaction. In addition, the Authority

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2020/996 of 9 July 2020 concerning the authorisation of the preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species reared for laying (holder of authorisation Biomin GmbH) (OJ L 221, 10.7.2020, p. 87).

⁽³⁾ EFSA Journal 2022; 20(9):7429.

⁽⁴⁾ EFSA Journal 2019;17(6):5724.

⁽⁵⁾ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

concluded that the additive has the potential to be efficacious in chickens for fattening. This conclusion could be extrapolated to turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and minor poultry species reared for breeding. In the absence of sufficient data, it could not conclude on the efficacy for laying hens or for other poultry species for laying or breeding. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of the preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and minor poultry species reared for breeding. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of that additive.
- (6) 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

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 20 March 2023.

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)									
4d20	Biomin GmbH	Preparation of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol	<i>Additive composition</i> Preparation of: — carvacrol (120-160 mg/g) — thymol (1-3 mg/g) — D-carvone (3-6 mg/g) — methyl salicylate (10-35 mg/g) — L-menthol (30-55 mg/g) — amorphous silica (maximum 100 mg/g) — hydrogenated vegetable oil (maximum 700 mg/g) Solid encapsulated form <i>Characterisation of the active substance</i> Carvacrol (CAS number: 499-75-2) Thymol (CAS number: 89-83-8) D-Carvone (CAS number: 2244-16-8) Methyl salicylate (CAS number: 119-36-8) - L-Menthol (CAS number: 2216-51-8) <i>Analytical method</i> ⁽¹⁾ For the quantification of the active substances: Gas chromatography coupled with flame ionisation detection (GC-FID).	Turkeys for fattening Turkeys reared for breeding Minor poultry species for fattening Minor poultry species reared for breeding	—	65	105	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall not be used with other sources of carvacrol, thymol, D-carvone, methyl salicylate and L-menthol. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. 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 and eye protection.	11.4.2033

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>