



2024/786

7.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/786

of 6 March 2024

concerning the authorisation of a preparation of thyme oil, star anise oil and quillaja bark powder as a feed additive for all poultry species for fattening (holder of authorisation: Delacon Biotechnik 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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of thyme oil, star anise oil and quillaja bark powder as a feed additive. 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 thyme oil, star anise oil and quillaja bark powder as a feed additive for all avian species, requesting that additive to be classified in the category 'zootechnical additives' and in the functional groups 'digestibility enhancers' and 'other zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 21 March 2023 ⁽²⁾ that, under the proposed conditions of use, the preparation of thyme oil, star anise oil and quillaja bark powder is safe for chickens for fattening and other poultry species for fattening, consumers and the environment. For long-living animals, the use of that additive was considered of concern owing to the presence of estragole. It also concluded that the preparation of thyme oil, star anise oil and quillaja bark powder is corrosive to the eyes but not irritant to skin, and may be a respiratory irritant or dermal or respiratory sensitiser. The Authority further concluded that the preparation of thyme oil, star anise oil and quillaja bark powder, under the proposed conditions of use, has the potential to be efficacious in improving the zootechnical performance of chickens for fattening. This conclusion was extrapolated to all poultry species for fattening, reared for laying or reared for breeding. Due to the lack of sufficient data, the Authority could not conclude on the efficacy of the preparation of thyme oil, star anise oil and quillaja bark powder as a zootechnical additive for laying hens and, consequently, for other laying poultry species. It did not consider that there is a need for specific requirements of post-market monitoring. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ⁽³⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the active substance thymol in animal feed ⁽⁴⁾ are valid and applicable for the current application.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2023;21(4):7955.

⁽³⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

⁽⁴⁾ EURL evaluation report available on the EURL website: https://joint-research-centre.ec.europa.eu/publications/fad-2011-0036_en.

- (5) The applicant withdrew the application on 17 July 2023 for the authorisation of the preparation of thyme oil, star anise oil and quillaja bark powder for all poultry species for breeding and laying, reared for laying and reared for breeding, and for ornamental birds, and on 19 October 2023 as regards the authorisation of that preparation in the functional group 'digestibility enhancers'.
- (6) In view of the above, the Commission considers that the preparation of thyme oil, star anise oil and quillaja bark powder satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for all poultry species for fattening. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) 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 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

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, 6 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed 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 the additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)									
4d15i	Delacon Biotechnik GmbH	Thyme oil, star anise oil and quillaja bark powder	<p><i>Additive composition</i></p> <p>Preparation of:</p> <ul style="list-style-type: none"> — Partially microencapsulated essential oils of thyme (<i>Thymus vulgaris</i> L.) and star anise (<i>Illicium verum</i> L.): ≥ 74 mg/g — Quillaja (<i>Quillaja saponaria</i>) bark powder: ≥ 200 mg/g — Crushed dried herbs and spices: 250-300 mg/g. <p>Solid form.</p> <p><i>Characterisation of the active substances</i></p> <p>Thyme oil:</p> <ul style="list-style-type: none"> — Thymol (CAS no 89-83-8): ≥ 25 % — Carvacrol (CAS No 499-75-2): 1-10 % <p>Star anise oil:</p> <ul style="list-style-type: none"> — <i>Trans</i>-anethole (CAS No 4180-23-8): 86-93 % — <i>Cis</i>-anethole (CAS No 25679-28-1): 0,1-0,5 % — Estragole (CAS No 140-67-0): 0,3-6,6 % — Safrole (CAS No 94-59-7): ≤ 0,1 %. 	All poultry species for fattening	—	150	150	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Mixture with other additives is permitted provided that the amounts of thymol, carvacrol, estragole and safrole added to feedingstuffs by such mixtures is lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or category of animals. 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment. 	27 March 2034

			Quillaja bark powder: Saponins (CAS No 8047-15-2): about 10 %. <i>Analytical method</i> ⁽¹⁾ Quantification of thymol (phytochemical marker) in the feed additive, in premixtures and in compound feed: gas chromatography-mass spectrometry (GC/MS)						
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⁽¹⁾ Details of the analytical methods 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