COMMISSION IMPLEMENTING REGULATION (EU) 2024/750

of 29 February 2024

concerning the renewal of the authorisation of thaumatin as a feed additive for all animal species and repealing Implementing Regulation (EU) No 869/2012

(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 and renewing such an authorisation.

(2) Thaumatin was authorised for 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 869/2012 ([2]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of thaumatin as a feed additive, requesting the feed additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The application included a proposal for amending the conditions of the original authorisation. It consisted of a modification of the specifications for nitrogen and protein in the additive, in order to align them to the specifications for thaumatin when used as a food additive (not less than 15,1 % nitrogen (N) on the dried basis and not less than 93 % protein). That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 May 2023 ([3]) that thaumatin remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. In particular, it concluded that the proposed modification of the specifications of the additive would not add any hazard to those already assessed and is not considered to have an impact on the efficacy of the substance. The Authority further concluded that the exposure of users to thaumatin via inhalation is likely and that, due to its proteinaceous nature, thaumatin is considered a respiratory sensitiser. According to the Authority, thaumatin is not a skin or an eye irritant. In the absence of data, the Authority could not conclude on the dermal sensitisation potential of thaumatin.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of thaumatin as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ([4]), an evaluation report of the Reference Laboratory is therefore not required.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) Commission Implementing Regulation (EU) No 869/2012 of 24 September 2012 concerning the authorisation of thaumatin as a feed additive for all animal species (OJ L 257, 25.9.2012, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2012/869/oj).
([3]) *EFSA Journal* 2023;21(6):8077.
([4]) 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, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

(6) In view of the above, the Commission considers that thaumatin satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(7) Certain conditions should be provided for to allow better control. In particular, a recommended maximum content should be indicated on the label of the additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(8) As a consequence of the renewal of the authorisation of thaumatin as a feed additive, Implementing Regulation (EU) No 869/2012 should be repealed.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of thaumatin for all animal species, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of 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

Renewal of authorisation

The authorisation of the additive specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 869/2012

Implementing Regulation (EU) No 869/2012 is repealed.

Article 3

Transitional measures

1. The substance specified in the Annex and premixtures containing that substance which are produced and labelled before 21 September 2024 in accordance with the rules applicable before 21 March 2024 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance specified in the Annex, which are produced and labelled before 21 March 2025 in accordance with the rules applicable before 21 March 2024 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substance specified in the Annex, which are produced and labelled 21 March 2026 in accordance with the rules applicable before 21 March 2024 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 4

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, 29 February 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	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 feedingstuff with a moisture content of 12 %			
Category: sensory additives. Functional group: flavouring compounds								
2b957i	Thaumatin	*Additive composition* Thaumatin *Characterisation of the active substance* Proteins thaumatin I and thaumatin II extracted from the arils of the fruit *Thaumatococcus daniellii* (Benth) Einecs: 258-822-2 CAS number: 53850-34-3 *Specifications* Chemical formula: Polypeptide of 207 aminoacids Relative molecular mass: Thaumatin I: 22209, Thaumatin II: 22293 Assay: min 15,1 % nitrogen on the dried basis equivalent to not less than 93 % protein Purity: — Carbohydrates: not more than 3 % expressed on dry weight basis — Sulphated ash: not more than 2 % expressed on dry matter basis	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 2. On the label of the additive, the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: 5 mg.' 3. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 2.	21 March 2034

		— Aluminium: not more than 100 mg/kg expressed on dry matter basis *Method of analysis* ([1]) Identification of the thaumatin in the feed additive: Nitrogen content in the food additive Kjeldahl method (JECFA Monograph on Thaumatin. 2006. Thaumatin. Specification Monograph).					4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the 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 and skin protective equipment.	

([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