



**COMMISSION IMPLEMENTING REGULATION (EU) 2024/285**

**of 17 January 2024**

**concerning the authorisation of taiga root tincture from *Eleutherococcus senticosus* (Rupr. & Maxim.)  
Maxim as a feed additive for dogs, cats and horses**

**(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. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC (²).
- (2) The substance taiga root tincture from *Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. This substance was subsequently entered in the Register of Feed Additives as an existing product belonging to the category 'sensory additives' and to the functional group 'flavouring compounds', in accordance with Article 10(1), point (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 authorisation of taiga root tincture from *Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim as a feed additive for all animal species, requesting 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.
- (4) The applicant subsequently withdrew the application for authorisation of *Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim as regards the use for all animal species except dogs, cats and horses.
- (5) The applicant requested the additive to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of this additive in water for drinking should not be allowed.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 February 2023 (³) that, under the proposed conditions of use, taiga root tincture from *Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim is safe for dogs, cats and horses, for consumers and for the environment. It concluded that taiga root tincture from *Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitisers. The Authority further concluded that it is recognised that the substance can influence sensory properties of feedingstuffs and that no further demonstration of efficacy is considered necessary for that substance. The Authority 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.

(¹) OJ L 268, 18.10.2003, p. 29.

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

(³) EFSA Journal 2023;21(2):7876

(7) In view of the above, the Commission considers that taiga root tincture from *Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. The Commission considers that for taiga root tincture from *Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim, the presence of substances of concern requires to set a maximum content in complete feed and to limit the combination of the additive with others containing the same substances of concern. 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.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of taiga root tincture from *Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(9) 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 an 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 that substance, which are produced and labelled before 7 August 2024 in accordance with the rules applicable before 7 February 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 7 February 2025 in accordance with the rules applicable before 7 February 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 before 7 February 2026 in accordance with the rules applicable before 7 February 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 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, 17 January 2024.

*For the Commission*

*The President*

Ursula VON DER LEYEN

## ANNEX

Identification number of the 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 active substance/kg of complete feed with a moisture content of 12 %			

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

2b84696-t	Taiga root tincture	<p><i>Additive composition</i> Tincture from roots and dried rhizome of <i>Eleutherococcus senticosus</i> (Rupr. &amp; Maxim.) Maxim. Liquid form</p> <p><i>Characterisation of the active substance</i> Tincture obtained from the roots and dried rhizome of <i>Eleutherococcus senticosus</i> (Rupr. &amp; Maxim.) Maxim. by extraction with a water/ethanol mixture as defined the Council of Europe (1). CAS number: 84696-12-8</p> <p><i>Specifications:</i> Dry matter content: 0,5-1,5 % Lignans. maximum of 0,014 % — Syringaresinol-di-O-glucoside (eleutheroside E): 0,0001-0,005 % — Syringaresinol: 0,001 % — Unknown lignans: 0,006 % Sinapyl alcohol 4-O-glucoside (eleutheroside B, syringin): 0,0001-0,005 % Hydroxycoumarins: maximum of 0,001 %</p>	Dogs			460	<ol style="list-style-type: none"> <li>1. The additive shall be incorporated into the feed in the form of a premixture.</li> <li>2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated.</li> <li>3. Mixture of taiga root tincture with other botanical additives is permitted provided that the amount of hydroxycoumarins and lignans in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum level for the species or animal category.</li> <li>4. 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.</li> </ol>	7 February 2034
			Cats			489		
			Horses			140		

		<p><i>Analytical method</i> (2)</p> <p>For the determination of eleutheroside B and eleutheroside E (phytochemical markers) in the feed additive (taiga root tincture):</p> <ul style="list-style-type: none"><li>— high performance liquid chromatography coupled with photometric detection (HPLC-UV)</li></ul>					
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(1) Natural sources of flavourings – Report No 2 (2007).

(2) 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>