



2024/806

8.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/806

of 7 March 2024

concerning the authorisation of pine tincture from *Pinus sylvestris* L. as a feed additive for all 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 ⁽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 pine tincture from *Pinus sylvestris* L. was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species. That substance was subsequently entered in the Register of Feed Additives as an existing product, 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 pine tincture from *Pinus sylvestris* L. as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds' and to be authorised also for use in water for drinking. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 July 2023 ⁽³⁾ that, under the proposed conditions of use, pine tincture from *Pinus sylvestris* L. is safe for all animal species, consumers and the environment. Furthermore, the Authority stated that the further demonstration of efficacy is not necessary as twigs of *Pinus sylvestris* L. are used to flavour food and are considered similar in composition to the source material for the production of pine tincture. It concluded that pine tincture from *Pinus sylvestris* L. should be considered as irritant to skin and eyes, and as a dermal and respiratory sensitiser. 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.
- (5) In view of the above, the Commission considers that pine tincture from *Pinus sylvestris* L. 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 appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) In addition, in order to allow better control, flavourings should be incorporated in feed in the form of premixtures. The Commission considers that for pine tincture from *Pinus sylvestris* L., safety reasons do not require the setting of maximum levels. In order to allow better control, a recommended maximum content should be indicated on the label of the additive. Where the recommended maximum content is exceeded, certain information should be indicated on the label of the premixtures concerned.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

⁽³⁾ EFSA Journal 2023;21(7):8181.

- (7) Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of that additive in water for drinking should not be allowed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of pine tincture from *Pinus sylvestris* L., 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 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 that substance, which are produced and labelled before 28 September 2024 in accordance with the rules applicable before 28 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 28 March 2025 in accordance with the rules applicable before 28 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 before 28 March 2026 in accordance with the rules applicable before 28 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 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, 7 March 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 active substance/kg of complete feed with a moisture content of 12 %			
Category: sensory additives. Functional group: flavouring compounds								
2b2816792-t	Pine tincture	<p><i>Additive composition</i></p> <p>Pine tincture from the buds of <i>Pinus sylvestris</i> L.</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Dry matter content: 1,9-2,5 %</p> <p>Pine tincture from the buds of <i>Pinus sylvestris</i> L. by extraction with a water/ethanol mixture as defined by the Council of Europe ⁽¹⁾.</p> <p>EC number: 281-679-2 ⁽²⁾</p> <p><i>Specifications</i></p> <ul style="list-style-type: none">— Polyphenols: 0,070–0,102 %— Phenolic acids: 0–0,038 %— Rutin: 0-0,001 %— Ferulic acid: 0,0003–0,0006 %— α-Terpineol: 0,00013-0,00025 % <p><i>Analytical method</i> ⁽³⁾</p> <p>For the characterisation of the feed additive: spectrophotometry for the determination of total polyphenols: high performance thin-layer chromatography (HPTLC) for the determination of total phenolic acids.</p>	All animal species	—	—	—	<ol style="list-style-type: none">1. The additive shall be incorporated into the feed in the form of a premixture.2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated.3. 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 %: 50 mg.'4. 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 3.5. 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, eye and skin protective equipment.	28 March 2034

⁽¹⁾ Natural sources of flavourings – Report No 2 (2007).

⁽²⁾ EC number covering Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from *Pinus sylvestris*, *Pinaceae*. Source: ECHA Database.

⁽³⁾ 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>.
