



2024/824

11.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/824

of 8 March 2024

concerning the authorisation of gentian tincture from *Gentiana lutea* L. as a feed additive for certain 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) and Article 10(5) 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 gentian tincture from *Gentiana lutea* 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 gentian tincture from *Gentiana lutea* 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'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) 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 the additive in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 18 March 2021 ⁽³⁾ and 1 February 2023 ⁽⁴⁾ that, under the proposed conditions of use, gentian tincture from *Gentiana lutea* L. is safe for short-living animals, i.e., animal species for fattening, for consumers and for the environment. It stated that no conclusions could be drawn for long-living animals and reproductive animals in the absence of data on the *in vivo* genotoxicity of xanthenes (gentisin and isogentisin) and gentiopicroside. Furthermore, the Authority could not conclude on the potential of the additive to be a dermal/eye irritant or a skin sensitiser, in the absence of data. It also noted that when handling the tincture, exposure of unprotected users to the potential genotoxicants xanthenes (gentisin and isogentisin) and gentiopicroside cannot be excluded and that therefore, to reduce the risk, the exposure of the users should be minimised. In addition, the Authority concluded that since gentian tincture from *Gentiana lutea* L. is recognised to flavour food and since its function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽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 2021;19(4):6547.

⁽⁴⁾ EFSA Journal 2023;21(2):7869.

- (6) Subsequently, the applicant withdrew the application for authorisation of gentian tincture from *Gentiana Lutea* L. for all animal species and categories except: animal species for fattening (other than Equidae) and salmonids and minor fin fish other than brood stock.
- (7) In view of the above, the Commission considers that gentian tincture from *Gentiana lutea* L. satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, as regards animal species for fattening (except Equidae), salmonids and fin fish except brood stock, and provided in particular that the additive is not used in combination with other additives containing gentisin, isogentisin and gentiopicroside. Accordingly, the use of that substance should be authorised. 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) Article 10(5) of Regulation (EC) No 1831/2003 imposes an obligation on the Commission to adopt a Regulation requiring the withdrawal from the market of feed additives for which no applications as required by Article 10(2) of Regulation (EC) No 1831/2003 were submitted before the deadline provided for in that provision. Similarly, a Regulation should be adopted concerning feed additives for which an application was submitted but subsequently withdrawn.
- (9) In the case of feed additives for which an application has been withdrawn only for certain animal species or categories, the withdrawal from the market should only concern those animal species or categories.
- (10) Therefore, gentian tincture from *Gentiana lutea* L. should be withdrawn from the market as regards the animal species and categories which are not the subject of the authorisation granted by this Regulation.
- (11) In so far as this Regulation authorises gentian tincture from *Gentiana lutea* L. as a feed additive, safety reasons do not require the immediate application of the modifications to the conditions of authorisation of that substance in respect of the animal species and categories which are covered by the authorisation granted by this Regulation. It is therefore appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (12) In addition, in so far as the feed additive is withdrawn from the market, it is also appropriate to allow for a transitional period within which existing stocks of the additive, premixtures, feed materials and compound feed which have been produced with that additive, may be used up also in respect of the animal species and categories of animals which are not covered by the authorisation granted by this Regulation, in order to allow interested parties to adapt to the obligation to withdraw those products from the market.
- (13) 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

Withdrawal from the market

The feed additive gentian tincture from *Gentiana lutea* L., as authorised pursuant to Directive 70/524/EEC, shall be withdrawn from the market in respect of the animal species and categories other than those mentioned in the Annex.

*Article 3***Transitional measures related to the authorisation**

1. The feed additive referred to in Article 2 and premixtures containing that additive, which are produced and labelled before 30 September 2024 in accordance with the rules applicable before 31 March 2024, may continue to be placed on the market and used in respect of the animal species and categories mentioned in the Annex until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in Article 2, which are produced and labelled before 31 March 2025 in accordance with the rules applicable before 31 March 2024, may continue to be placed on the market and used in respect of the animal species and categories mentioned in the Annex until the stocks concerned are exhausted.

*Article 4***Transitional measures related to the withdrawal from the market**

1. Existing stocks of the feed additive referred to in Article 2 may continue to be placed on the market and used in respect of the animal species and categories other than those mentioned in the Annex until 31 March 2025.
2. Premixtures produced with the feed additive referred to in paragraph 1 may continue to be placed on the market and used in respect of the animal species and categories other than those mentioned in the Annex until 30 June 2025.
3. Compound feed and feed materials produced with the feed additive referred to in paragraph 1 or with the premixtures referred to in paragraph 2 may continue to be placed on the market and used in respect of the animal species and categories other than those mentioned in the Annex until 31 March 2026.

*Article 5***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, 8 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

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

2b2506-t	Gentian tincture	<p><i>Additive composition</i></p> <p>Tincture from roots of <i>Gentiana lutea</i> L.</p> <p>Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Tincture obtained from the roots of <i>Gentiana lutea</i> L. by extended extraction with a water/ethanol mixture as defined the Council of Europe (!).</p> <p>FEMA number: 2506</p> <p><i>Specifications</i></p> <p>Dry matter: 3,5-5 %</p> <p>Total polyphenols: 0,05-0,11 %</p> <p>Total flavonoids:0,03-0,06 %</p> <p>Xanthones: maximum 0,004 %</p> <p>— Gentisin</p> <p>— Isogentisin</p> <p>Gentiopicroside: maximum 0,006 %</p>	<p>Pigs for fattening and pigs for fattening of minor <i>Suidae</i></p> <p>Cattle for fattening, sheep for fattening, minor ruminants for fattening and calves for fattening</p> <p>Chickens for fattening, turkeys for fattening and minor poultry for fattening</p> <p>Salmonids and minor finfish except brood stock</p> <p>Other minor species for fattening except Equidae</p>	—	—	50	<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. This additive shall not be used in combination with other additives containing gentisin, isogentisin and gentiopicroside. 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, eye and skin protective equipment. 	31 March 2034
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	<p><i>Analytical method</i> ⁽²⁾</p> <p>For the identification and characterisation of the feed additive:</p> <ul style="list-style-type: none"> — Gravimetry for the determination of dry matter and ash content; — Spectrophotometry for the determination of total polyphenols content; and — High performance thin-layer chromatography (HPTLC) for the determination of contents of total flavonoids, xanthones (gentisin and isogentisin) and gentiopicroside. 						
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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>