



2025/152

30.1.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/152

of 29 January 2025

concerning the authorisation of omicha tincture from *Schisandra chinensis* (Turcz.) Baill. and ginseng tincture from *Panax ginseng* C.A.Mey. as feed additives 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) 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 substances omicha tincture from *Schisandra chinensis* (Turcz.) Baill and ginseng tincture from *Panax ginseng* C.A.Mey. were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those substances were subsequently entered in the Register of Feed Additives as existing products, 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 omicha tincture from *Schisandra chinensis* (Turcz.) Baill. and ginseng tincture from *Panax ginseng* C.A.Mey. as feed additives for all animal species, requesting the additives 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 subsequently withdrew the application for authorisation of omicha tincture from *Schisandra chinensis* (Turcz.) Baill. as regards the use for all animal species except horses, dogs, cats, poultry, and for authorisation of ginseng tincture from *Panax ginseng* C.A.Mey. as regards the use for all animal species except horses, cats and dogs.
- (5) The applicant requested the substances concerned 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 these additives in water for drinking should not be allowed.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinions of 12 March 2024 ⁽³⁾ and 13 March 2024 ⁽⁴⁾ that omicha tincture from *Schisandra chinensis* (Turcz.) Baill. is safe for horses, dogs, cats, poultry and consumers at certain maximum concentrations further specified for each species and that ginseng tincture from *Panax ginseng* C.A.Mey. is safe for horses, dogs, cats and consumers at the proposed use level in feed. It also found that the use of omicha tincture from *Schisandra chinensis* (Turcz.) Baill and ginseng tincture from *Panax ginseng* C.A.Mey. in animal feed, is not considered to pose a risk to the environment. The Authority concluded that omicha tincture from *Schisandra chinensis* (Turcz.) Baill. and ginseng tincture from *Panax ginseng* C.A.Mey should be

⁽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. 2024;22:e8730.

⁽⁴⁾ EFSA Journal. 2024;22:e8731.

considered as irritants to skin and eyes, and as skin and respiratory sensitisers. The Authority further concluded that since the fruit of *Schisandra chinensis* (Turcz.) Baill can influence sensory properties of feedingstuffs, and since the roots of *Panax ginseng* C.A.Mey. and their preparations and extracts are recognised to flavour food and their 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.

- (7) In view of the above, the Commission considers that omicha tincture from *Schisandra chinensis* (Turcz.) Baill. and ginseng tincture from *Panax ginseng* C.A.Mey. satisfy the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of those substances should be authorised as specified in the Annex to this Regulation. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives.
- (8) The Commission considers that safety reasons do not require the setting of maximum levels for omicha tincture from *Schisandra chinensis* (Turcz.) Baill and ginseng tincture from *Panax ginseng* C.A.Mey. In order to allow better control, the recommended maximum content should be indicated on the label of the feed additives. Where the recommended maximum content is exceeded, certain information should be indicated on the label of the premixtures concerned.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from 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

Authorisation

The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. The feed additives omicha tincture from *Schisandra chinensis* (Turcz.) Baill. and ginseng tincture from *Panax ginseng* C. A. Mey., as authorised pursuant to Directive 70/524/EEC and premixtures containing these additives, which are produced and labelled before 19 August 2025 in accordance with the rules applicable before 19 February 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before 19 February 2026 in accordance with the rules applicable before 19 February 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before 19 February 2027 in accordance with the rules applicable before 19 February 2025 may continue to be placed on the market and used until the stocks concerned 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, 29 January 2025.

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 of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b61281-t	Omicha tincture	Additive composition	Dogs	—	—	—	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 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 %: — 12 mg for chickens for fattening, minor poultry for fattening and all poultry reared for laying or reared for breeding, — 18 mg for all poultry species for laying or breeding,	19 February 2035
		Omicha tincture from the fruit of <i>Schisandra chinensis</i> (Turcz.) Baill.	Cats	—	—	—		
		Liquid form						
		Characterisation of the active substance	Horses	—	—	—		
		Omicha tincture						
		Tincture as defined by the Council of Europe ⁽¹⁾ obtained from the dried fruit of <i>Schisandra chinensis</i> (Turcz.) Baill. by extraction with water/ethanol solvent mixture, pressing and filtration.	Poultry	—	—	—		
		Specifications						
		— Dry matter content: maximum 4 % — Sum of schisandrin and deoxyschisandrin: 0,01-0,15 %						
		Analytical method ⁽²⁾						
		For the determination of schisandrin and deoxyschisandrin (phytochemical markers) in the feed additive: — high performance liquid chromatography coupled with photometric detection (HPLC-UV)						

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
							— 16 mg for turkeys for fattening, — 47 mg for horses and for cats, — 56 mg for dogs.’. 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 levels on the label of the premixture would result in exceeding the levels 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 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 skin, eye and breathing protective equipment.	

(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://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
2b318-t	Ginseng tincture	Additive composition	Horses	—	—	—	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 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 %:'	19 February 2035
		Ginseng tincture from the roots of <i>Panax ginseng</i> C.A.Mey.	Dogs	—	—	—		
		Liquid form	Cats	—	—	—		
		Characterisation of the active substance						
		Ginseng tincture						
		Tincture as defined by the Council of Europe ⁽¹⁾ obtained from the roots of <i>Panax ginseng</i> C.A.Mey by extraction with water/ ethanol solvent mixture, pressing and filtration.						
		CoE number: 318						
		Specifications						
		— Dry matter content: maximum: 6 %						
		— Sum of ginsenoside Rg1 and ginsenoside Rb1: 0,01-0,5 %						

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds								
		<i>Analytical method</i> ⁽²⁾ For the determination of ginsenoside-Rg1 and ginsenoside-Rb1 (phytochemical markers) in the feed additive: — high performance liquid chromatography coupled with photometric detection (HPLC-UV)					— 48 mg for horses; — 228 mg for dogs; — 162 mg for cats.’. 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 levels on the label of the premixture would result in exceeding the levels 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 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 skin, eye and breathing protective equipment.	

⁽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://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en