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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**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)

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COMMISSION IMPLEMENTING REGULATION (EU) .../...

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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 nutrition¹, 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/EEC².
- (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

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>).

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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 opinions of 12 March 2024³ and 13 March 2024⁴ 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 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 substance 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,

³ EFSA Journal. 2024;22:e8730.
⁴ EFSA Journal. 2024;22:e8731.

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 [6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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 [12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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 [24 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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,

For the Commission
The President
Ursula VON DER LEYEN