



2023/2846

21.12.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2846

of 20 December 2023

concerning the authorisation of red quebracho extract from *Schinopsis balansae* Engl. or *Schinopsis lorentzii* (Griseb.) Engl. 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 red quebracho extract from *Schinopsis balansae* Engl. or *Schinopsis lorentzii* (Griseb.) Engl. 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 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 red quebracho extract from *Schinopsis balansae* Engl. or *Schinopsis lorentzii* (Griseb.) Engl. 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'. 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 this additive in water for drinking should not be allowed.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 22 November 2022 ⁽³⁾ that, under the proposed conditions of use, red quebracho extract from *Schinopsis balansae* Engl. or *Schinopsis lorentzii* (Griseb.) Engl. is safe for all animal species, for consumers and the environment. It also concluded that the extract under assessment is not an eye irritant but that in the absence of data, no conclusion can be drawn on its potential to be a skin irritant and a dermal and respiratory sensitiser. It further concluded that since the substance 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 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 2022;20(12):7699.

- (6) In view of the above, the Commission considers that red quebracho extract from *Schinopsis balansae* Engl. or *Schinopsis lorentzii* (Griseb.) Engl. satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of this substance should be authorised. The Commission considers that due to the possible effect of this extract as medicinal product and other possible zootechnical effects thereof, a maximum level should be set in order to prevent this additive from being used for other purposes. 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.
- (7) 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.
- (8) 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 10 July 2024 in accordance with the rules applicable before 10 January 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 10 January 2025 in accordance with the rules applicable before 10 January 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 10 January 2026 in accordance with the rules applicable before 10 January 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, 20 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

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

2b2972-ex	Red quebracho extract	Additive composition Wood extract of either <i>Schinopsis balansae</i> Engl. or <i>Schinopsis lorentzii</i> (Griseb.) Engl. Solid form	Turkeys for fattening	—	—	540	- The additive shall be incorporated into the feed in the form of a premixture. - In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. - Mixture of red quebracho extract with other botanical additives is permitted provided that the amounts of condensed tannins in feed materials and compound feed are lower than the one resulting from the use of a single additive at the maximum or recommended level for the species or animal category.	10 January 2034
		Characterisation of the active substance Extract of condensed tannins from red quebracho	Chickens for fattening and minor poultry for fattening	—	—	400		
		Extract obtained from wood of either <i>Schinopsis balansae</i> Engl. or <i>Schinopsis lorentzii</i> (Griseb.) Engl. by steam under pressure, further filtration, concentration and spray drying of the concentrated solution as defined by the Council of Europe ⁽¹⁾	All poultry species for laying and breeding purposes.	—	—	600		
		Specifications Condensed tannins: 70-87 % CAS number: 90106-04-0 for <i>Schinopsis lorentzii</i> (Griseb.) Engl. FEMA number: 2972	Piglets, piglets of minor <i>Suidae</i> and pigs for fattening of minor <i>Suidae</i>	—	—	720		
			Pigs for fattening	—	—	860		
			Sows	—	—	1 050		
			Veal calves (milk replacer)	—	—	1 680		

Analytical method ⁽²⁾ For the quantification of condensed tannins (phytochemical marker) in the feed additive: indirect gravimetric analysis of tanning agents with fixing of the absorbent compounds in low chromed hide powder – ISO 14088	Ruminants for fattening except sheep and goats	—	—	1 580	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.
	Horses	—	—	1 580	
	Sheep, goats	—	—	1 580	
	Dairy cows and minor dairy ruminants except dairy sheep and goat	—	—	1 030	
	Rabbits	—	—	630	
	Salmonids and minor finfish	—	—	1 810	
	Ornamental fish	—	—	3 000	
	Dogs	—	—	1 900	
	Ornamental birds			317	
	Cats	—	—	317	
	Other animal species and categories	—	—	317	

⁽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>