



2024/749

1.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/749
of 29 February 2024
concerning the authorisation of lignosulphonate 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 an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Lignosulphonate 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)(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 re-evaluation of lignosulphonate as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'technological additives' and in the functional group 'binders'. The 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 opinions of 6 July 2015 ⁽³⁾, 10 January 2020 ⁽⁴⁾ and 21 March 2023 ⁽⁵⁾ that, under the proposed conditions of use, lignosulphonate is safe for weaned piglets, pigs for fattening, chickens for fattening, laying hens and cattle for fattening at a maximum content of 10 000 mg/kg complete feed and for all other animal species at a maximum content of 8 000 mg/kg complete feed, for consumers and for the environment. It also concluded that solid forms of lignosulphonate should be regarded as hazardous by inhalation. The Authority further concluded that the additive is effective as a pellet binder. 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.
- (5) In view of the above, the Commission considers that lignosulphonate satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance 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 additive.
- (6) 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.

⁽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 2015;13(7):4160.

⁽⁴⁾ EFSA Journal 2020;18(2):6000.

⁽⁵⁾ EFSA Journal 2023;21(4):7956.

- (7) 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 'technological additives' and to the functional group 'binders', 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 21 September 2024 in accordance with the rules applicable before 21 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 21 March 2025 in accordance with the rules applicable before 21 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 21 March 2026 in accordance with the rules applicable before 21 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, 29 February 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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 of the additive/kg of complete feed with a moisture content of 12 %			
Category: technological additives. Functional group: binders								
1g565	Lignosulphonate	<i>Additive composition</i> Calcium, sodium or magnesium lignosulphonate: ≥ 55 % Reducing sugars: ≤ 20 % (on a dry matter basis) The content of reducing sugars is reached by ultrafiltration or by fermentation with <i>Saccharomyces cerevisiae</i> CBS 13806, <i>Saccharomyces cerevisiae</i> CBS 13807 or <i>Saccharomyces cerevisiae</i> CBS 13808 Solid or liquid form <i>Characterisation of the active substance</i> Amorphous branched polymers of lignin, containing sulphonated covalently linked phenyl propane monomers (C9).	Weaned piglets, pigs for fattening, chickens for fattening, laying hens, cattle for fattening	–	–	10 000	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive (in solid form) 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 breathing protective equipment.	21 March 2034
			All other animal species and categories			8 000		

		<i>Analytical method ⁽¹⁾</i> For the determination of lignosulphonate in the feed additive: — indirect determination by total ash and reducing sugars from JECFA monograph (40-65 – new specification for calcium ligno- sulfonate).						
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⁽¹⁾ 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