



2024/1730

21.6.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1730

of 20 June 2024

concerning the authorisation of benzoic acid as a feed additive for weaned piglets and pigs for fattening (holder of authorisation: LANXESS Chemical B.V.)

(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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of benzoic acid as a feed additive. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of benzoic acid as a feed additive for weaned piglets and pigs for fattening, requesting that additive to be classified in the category 'zootechnical additives', in the functional group 'other zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 November 2023 ⁽²⁾ that, under the proposed conditions of use, benzoic acid is safe for weaned piglets and pigs for fattening, consumers and the environment. It also concluded that benzoic acid poses a risk by inhalation, is irritant to skin and corrosive to eyes, but that due to the lack of data no conclusions can be drawn on dermal sensitisation. The Authority further concluded that benzoic acid is efficacious as a zootechnical feed additive for weaned piglets up to 25 kg and for pigs for fattening. It did not consider that there is a need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ⁽³⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same active substance ⁽⁴⁾ are valid and applicable for the current application.
- (6) In view of the above, the Commission considers that benzoic acid satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. It is appropriate to provide for the additive not to be used with other sources of benzoic acid or benzoates, and to be fed only thoroughly mixed with other feed materials of the daily ration. 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) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ EFSA Journal. 2023;21:e8454.

⁽³⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

⁽⁴⁾ Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/publications/fad-2010-0029_en.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	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 active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters: weight gain or feed to gain ratio)									
4d211	LANXESS Chemical B.V.	Benzoic acid	<i>Additive composition</i> Benzoic acid (≥ 99,9 %) Solid form. <i>Characterisation of the active substance</i> Benzoic acid (also known as benzenecarboxylic acid and phenylcarboxylic acid) C₇H₆O₂ CAS number: 65-85-0 Maximum level of the impurities: Phthalic acid: ≤ 100 mg/kg Biphenyl: ≤ 100 mg/kg <i>Analytical method ⁽¹⁾</i> For the determination of benzoic acid in the feed additive, premixtures and compound feed: high performance liquid chromatography with ultraviolet detection (HPLC-UV) – EN 17298	Weaned pig-lets	—	5 000	5 000	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall not be used with other sources of benzoic acid or benzoates. 3. In the directions for use of the additive, premixtures and compound feed the following shall be indicated: 'Complementary feedingstuff containing benzoic acid shall only be fed to weaned pig-lets if thoroughly mixed with other feed materials of	11 July 2034

								the daily ration’. 4. The additive shall only be used in weaned piglets up to 25 kg of body weight. 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 breathing, eye and skin protective equipment.	
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Category: zootechnical additives. Functional group: other zootechnical additives (urinary pH decrease)									
4d211	LANXESS Chemical B.V.	Benzoic acid	<i>Additive composition</i> Benzoic acid (≥ 99,9 %) Solid form. <i>Characterisation of the active substance</i> Benzoic acid (also known as benzenecarboxylic acid and phenylcarboxylic acid) C₇H₆O₂ CAS number: 65-85-0 Maximum level of the impurities: Phthalic acid: ≤ 100 mg/kg Biphenyl: ≤ 100 mg/kg <i>Analytical method (*)</i> For the determination of benzoic acid in the feed additive, premixtures and compound feed: high performance liquid chromatography with ultraviolet detection (HPLC-UV) – EN 17298	Pigs for fattening	—	5 000	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. The additive shall not be used with other sources of benzoic acid or benzoates. 3. In the directions for use of the additive, premixtures and compound feed the following shall be indicated: 'Complementary feedingstuff containing benzoic acid shall only be fed to pigs for fattening if thoroughly mixed with other feed materials of the daily ration'. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their	11 July 2034

								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.	
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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.