

COMMISSION IMPLEMENTING REGULATION (EU) 2016/900**of 8 June 2016****concerning the authorisation of benzoic acid as a feed additive for sows (holder of authorisation DSM Nutritional Product Sp. z o. o.)****(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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of benzoic acid. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of the benzoic acid as a feed additive for sows, to be classified in the additive category 'zootechnical additives'.
- (4) That additive was already authorised as a feed additive for use in weaned piglets by Commission Regulation (EC) No 1730/2006 ⁽²⁾ and in pigs for fattening by Commission Regulation (EC) No 1138/2007 ⁽³⁾.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 14 June 2012 ⁽⁴⁾ and 16 June 2015 ⁽⁵⁾ that, under the proposed conditions of use, the benzoic acid does not have an adverse effect on animal health, human health or the environment, and that it has a potential to introduce a small reduction in urine pH in sows. The Authority does not consider that there is a need for specific requirements of post-market monitoring. 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.
- (6) The assessment of the benzoic acid shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (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

The additive 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 1730/2006 of 23 November 2006 concerning the authorisation of benzoic acid (VevoVital) as a feed additive (OJ L 325, 24.11.2006, p. 9).

⁽³⁾ Commission Regulation (EC) No 1138/2007 of 1 October 2007 concerning the authorisation of a new use of benzoic acid (VevoVital) as a feed additive (OJ L 256, 2.10.2007, p. 8).

⁽⁴⁾ EFSA Journal 2012;10(7):2775.

⁽⁵⁾ EFSA Journal 2015;13(7):4157.

Article 2

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, 8 June 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the 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/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (urinary pH decrease)									
4d210	DSM Nutritional Products Sp. z o. o.	Benzoic acid	<p>Additive composition</p> <p>Benzoic acid ($\geq 99,9\%$)</p> <p><i>Characterisation of the active substance</i></p> <p>Benzenecarboxylic acid, phenylcarboxylic acid, C₇H₆O₂ CAS number 65-85-0</p> <p>Maximum level of the impurities:</p> <p>Phthalic acid: ≤ 100 mg/kg Biphenyl: ≤ 100 mg/kg</p> <p><i>Analytical method</i> (1)</p> <p>For the quantification of benzoic acid in the feed additive:</p> <p>— titration with sodium hydroxide (European Pharmacopoeia monograph 0066).</p> <p>For the quantification of the benzoic acid in the premixtures and feedingstuffs:</p> <p>— reversed phase liquid chromatography with UV detection (RP-HPLC/UV) — method based on ISO9231:2008.</p>	Sows	—	5 000	10 000	<p>1. The directions of use shall be indicated the following in complementary feed:</p> <p>‘Complementary feedingstuffs containing benzoic acid shall not be fed to sows as such. Complementary feedingstuffs for sows shall be thoroughly mixed with other feed materials of the daily ration’.</p> <p>2. For users of the additive and premixtures in a feed business, operational procedures and appropriate organisational measures shall be established to address hazards by inhalation, dermal contact or eyes contact. Where the dermal, inhalator or eyes exposure cannot be reduced to an acceptable level by these procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.</p>	29 June 2026

(1) 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>.