COMMISSION IMPLEMENTING REGULATION (EU) 2020/1031

of 15 July 2020

concerning the authorisation of benzoic acid as a feed additive for pigs for fattening (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional Products 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 benzoic acid as a feed additive for pigs for fattening, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 May 2019 ([2]) that, under the proposed conditions of use, benzoic acid does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is a skin irritant and severe eye irritant. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that benzoic acid has the potential to be efficacious improving the zootechnical performance in pigs for fattening. The Authority did 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.

(5) The assessment of 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.

(6) 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 preparation 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

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2019; 17(6):5727.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical parameters)									
4d210	DSM Nutritional Products Ltd represented by DSM Nutritional Products Sp. Z o. o	Benzoic acid	*Additive composition* Benzoic acid (≥ 99,9 %) ——————————————— *Characterisation of active substance* Benzenecarboxylic acid, phenylcarboxylic acid, $C_7H_6O_2$ CAS number 65-85-0 Maximum level of the impurities: Phthalic acid: ≤ 100 mg/kg Biphenyl: ≤ 100 mg/kg ——————————————— *Analytical method* (1) For the quantification of benzoic acid in the feed additive: — titration with sodium hydroxide (European Pharmacopoeia monograph 0066). For the quantification of the benzoic acid in the premixtures and feedingstuffs: – reversed phase liquid chromatography with UV detection (RP- HPLC/UV) – method based on ISO9231:2008	Pigs for fattening	-	3 000	10 000	1. In the directions for use of the additive and premixture, 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. The directions of use shall be indicated: 'Complementary feedingstuffs containing benzoic acid shall not be fed to pig for fattening as such. Complementary feedingstuff containing benzoic acid shall be 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 use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and eyes.	5 August 2030

(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