Commission Implementing Regulation (EU) 2018/1550 of 16 October 2018 concerning the renewal of the authorisation of benzoic acid as a feed additive for weaned piglets and pigs for fattening and repealing Regulations (EC) No 1730/2006 and (EC) No 1138/2007 (holder of authorisation DSM Nutritional Products Ltd) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1550

of 16 October 2018

concerning the renewal of the authorisation of benzoic acid as a feed additive for weaned piglets and pigs for fattening and repealing Regulations (EC) No 1730/2006 and (EC) No 1138/2007 (holder of authorisation DSM Nutritional Products Ltd)

(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 and renewing such authorisation.

(2) Benzoic acid was authorised for 10 years as a feed additive for weaned piglets by Commission Regulation (EC) No 1730/2006[(2)], and for pigs for fattening by Commission Regulation (EC) No 1138/2007[(3)].

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted by the holder of those authorisations for the renewal of the authorisation of benzoic acid as a feed additive, both for weaned piglets and for pigs for fattening, requesting that additive to be classified in the additive category ‘zootechnical additives’. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 28 November 2017[(4)] that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. 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 authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(5) As a consequence of the renewal of the authorisation of benzoic acid as a feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1730/2006 and (EC) No 1138/2007 should be repealed.

(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 authorisation of the additive specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, is renewed subject to the conditions laid down in that Annex.

Article 2

Regulations (EC) No 1730/2006 and (EC) No 1138/2007 are repealed.

Article 3

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, 16 October 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1550. (See end of Document for details)*

ANNEX

Identification number of the additive	**Name of the holder of authorisation**	**Additive**	**Composition, chemical formula, description, analytical method**	**Species or category of animal**	**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 zootechical parameters: weight gain or feed gain ratio)								
4d210	DSM Nutritional Products Ltd	Benzoic acid	*Additive composition* Benzoic acid (≥ 99,9 %) *Characterisation of the 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*[a] For the quantification of benzoic acid in	Piglets (weaned)	—	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. Recommended minimum dose: 5 000 mg/kg of complete feed. 3. The additive shall not be used with	5 November 2028

a 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

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1550. (See end of Document for details)*

			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 *Additive composition* Benzoic acid (≥ 99,9 %) *Characterisation of the active substance* Benzenecarboxylic acid, phenylcarboxylic acid, $C_7H_6O_2$ CAS number 65-85-0					other sources of benzoic acid or benzoates. 4. The directions of use shall be indicated: Complementary feedingstuffs containing benzoic acid shall not be fed to weaned piglets or pig for fattening as such. Complementary feedingstuffs shall be thoroughly mixed with other feed materials of the daily ration. 5. For use in weaned piglets

a 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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1550. (See end of Document for details)*

			Maximum level of the impurities: Phthalic acid: ≤ 100 mg/kg Biphenyl: ≤ 100 mg/kg *Analytical method*[a] 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				6.	up to 35 kg of body weight. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks concerning their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures

a 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