

COMMISSION IMPLEMENTING REGULATION (EU) 2022/538**of 4 April 2022****concerning the renewal of the authorisation of sodium benzoate as feed additive for weaned piglets, the new authorisation for weaned piglets of other *Suidae* and repealing Implementing Regulation (EU) No 496/2011 (holder of the authorisation Taminco Finland Oy)****(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) Sodium benzoate was authorised for 10 years as a feed additive for weaned piglets by Commission Implementing Regulation (EU) No 496/2011 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of the authorisation for the renewal of the authorisation of sodium benzoate for weaned piglets and for a new use for piglets of other *Suidae*, requesting that additive to be classified in the additive category 'zootechnical additives' and functional group 'other zootechnical additives'. That application was accompanied by the particulars and documents required under Article 7(3) and Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 September 2021 ⁽³⁾ that, under the proposed conditions of use, sodium benzoate does not have an adverse effect on the health of weaned piglets, consumer safety or the environment. This conclusion can be extended to other growing *Suidae*. The Authority concluded that the additive should be considered a skin sensitiser and that the powder formulation of the additive represents a risk by inhalation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Further, the Authority concluded based the efficacy data previously evaluated that the additive has the potential to be efficacious in weaned piglets. The conclusions on the efficacy reached in weaned piglets can be extended to other growing *Suidae* species at the corresponding physiological stage. 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.
- (5) The assessment of sodium benzoate 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 for weaned piglets and its use for piglets of other *Suidae* species at the corresponding physiological stage should be authorised, as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of sodium benzoate as a feed additive under the conditions laid down in the Annex to this Regulation, Implementing Regulation (EU) No 496/2011 should be repealed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 496/2011 of 20 May 2011 concerning the authorisation of sodium benzoate as a feed additive for weaned piglets as a feed additive (OJ L 134, 21.5.2011, p. 9).

⁽³⁾ EFSA Journal 2021;19(11):6899.

- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substance concerned, it is appropriate to provide a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.
- (8) 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 substance specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives' is authorised and renewed as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Implementing Regulation (EU) No 496/2011 is repealed.

Article 3

1. The substance referred to in Article 1 and premixtures containing it, which are produced and labelled before 25 October 2022 in accordance with the rules applicable before 25 April 2022 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substance referred to in paragraph 1, which are produced and labelled before 25 April 2023 in accordance with the rules applicable before 25 April 2022 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 4 April 2022.

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 feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical performances)									
4d5	Taminco Finland Oy	Sodium benzoate	Additive composition Granular or powder formulation with a minimum of 99 % sodium benzoate	Weaned piglets of all Suidae	-		4 000	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. Recommended minimum dose: 4 000 mg/kg of complete feed with a moisture content of 12 %. 4. The directions of use shall indicate: 'Complementary feed containing sodium benzoate shall not be fed to weaned piglets of all Suidae as such. Complementary feed containing sodium benzoate shall be thoroughly mixed with other compounds of the daily ration'.	25 April 2032
			Characterisation of active substance Sodium benzoate Chemical formula: C ₇ H ₅ O ₂ Na CAS number: 532-32-1						
			Analytical method ⁽¹⁾ For the determination of sodium benzoate (as total benzoic acid) in the feed additive, premixtures compound feed and feed materials: — High performance liquid chromatography with ultraviolet detection (HPLC-UV) – EN 17298 For the determination of total sodium in the feed additive:						

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						mg of active substance/kg of complete feed with a moisture content of 12 %			
			— Atomic absorption spectrometry (AAS) – EN ISO 6869; or — Inductively coupled plasma-atomic emission spectrometry (ICP-AES) – EN 15510					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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.	

⁽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>