

COMMISSION IMPLEMENTING REGULATION (EU) No 159/2013

of 21 February 2013

concerning the authorisation of a preparation of sodium benzoate, propionic acid and sodium propionate as a feed additive for pigs, poultry, bovines, sheep, goats, rabbits and horses and amending Regulations (EC) No 1876/2006 and (EC) No 757/2007

(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.
- (2) A preparation of sodium benzoate, propionic acid and sodium propionate was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on pigs and dairy cows by Commission Regulation (EC) No 1876/2006⁽³⁾ and for cattle for fattening by Commission Regulation (EC) No 757/2007⁽⁴⁾. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of that preparation of sodium benzoate, propionic acid and sodium propionate as a feed additive for pigs and dairy cows and cattle for fattening and, in accordance with Article 7 of that Regulation, for a new use for pigs, poultry, bovines, sheep, goats, rabbits and horses, requesting that additive to be classified in the additive category 'technological additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 6 September 2011⁽⁵⁾ and 24 April 2012⁽⁶⁾ that, under the proposed conditions of use, the preparation of sodium benzoate, propionic acid and sodium propionate does not have an adverse effect

on animal health, human health provided that adequate measures to protect users are taken, or the environment, and that it is efficacious in preserving cereals and complete feedingstuff. 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 the preparation of sodium benzoate, propionic acid and sodium propionate 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) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulations (EC) No 1876/2006 and (EC) No 757/2007 should therefore be amended accordingly.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1***Authorisation**

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

*Article 2***Amendments to Regulation (EC) No 1876/2006**

Article 4 of Regulation (EC) No 1876/2006 and Annex IV thereto are deleted.

*Article 3***Amendments to Regulation (EC) No 757/2007**

Article 1 of Regulation (EC) No 757/2007 and Annex I thereto are deleted.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 270, 14.12.1970, p. 1.

⁽³⁾ OJ L 360, 19.12.2006, p. 126.

⁽⁴⁾ OJ L 172, 30.6.2007, p. 43.

⁽⁵⁾ EFSA Journal 2011; 9(9):2357.

⁽⁶⁾ EFSA Journal 2012; 10(5):2681.

*Article 4***Transitional measures**

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 14 September 2013 in accordance with the rules applicable before 14 March 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

*Article 5***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, 21 February 2013.

For the Commission

The President

José Manuel BARROSO

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 technological additives. Functional group: preservatives

1a700	—	Preparation of sodium benzoate, propionic acid and sodium propionate	<p><i>Additive composition</i></p> <p>Preparation of:</p> <p>sodium benzoate: 140 g/kg, propionic acid: 370 g/kg sodium propionate: 110 g/kg Water: 380 g/kg</p> <p><i>Characterisation of the active substances</i></p> <p>Sodium benzoate (C₇H₅O₂Na) ≥ 99 % after drying of two hours at 105 °C Propionic acid (C₃H₆O₂) ≥ 99,5 % Sodium propionate (C₃H₅O₂Na) ≥ 99 % after drying of four hours at 105 °C</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Quantification in feed additive:</p> <p>— determination of benzoate: reversed phase chromatography with UV detection (HPLC-UV) — total propionate: ion exclusion High Performance Liquid Chromatography with refractive index (HPLC-RI) — total sodium: atomic absorption spectrometry, AAS (EN ISO 6869)</p>	Pigs Poultry Bovines Sheep Goats Rabbits Horses	—	—	10 000	<p>1. Simultaneous use with other sources of the active substances shall not exceed the authorised maximum content.</p> <p>2. Minimum content:</p> <p>— cereals with a moisture ≥ 15 % other than maize kernels: 3 000 mg/kg of cereals; — maize kernels with a moisture ≥ 15 %: 13 000 mg/kg of maize kernels; — complete feed with a moisture ≥ 12 %: 5 000 mg/kg of complete feed.</p> <p>3. Maximum content in all cereals: 22 000 mg/kg of cereals.</p> <p>4. For safety: it is recommended to use breathing and eyes protections and gloves during handling.</p>	14 March 2023
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx