Commission Implementing Regulation (EU) No 305/2014 of 25 March 2014 concerning the authorisation of propionic acid, sodium propionate and ammonium propionate as feed additives for all animal species other than ruminants, pigs and poultry (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 305/2014

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concerning the authorisation of propionic acid, sodium propionate and ammonium propionate as feed additives for all animal species other than ruminants, pigs and poultry

(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 propionic acid, sodium propionate and ammonium propionate. 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 propionic acid, sodium propionate and ammonium propionate as feed additives for all animal species to be classified in the additive category ‘technological additives’, functional group ‘silage additives’. The application includes also other uses of the same substances for which no decision has yet been taken. The additive was authorised for 10 years by Commission Implementing Regulation (EU) No 1222/2013[(2)] for ruminants, pigs and poultry.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 16 November 2011[(3)] that, under the proposed conditions of use, propionic acid, sodium propionate and ammonium propionate do not have an adverse effect on animal health, human health or the environment. It was also concluded that the substances improve the aerobic stability of easy to ensile materials. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the substances concerned shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those substances 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The substances specified in the Annex belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, are authorised as additives 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*.

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

Done at Brussels, 25 March 2014.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 305/2014. (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**	**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: silage additives									
1k280	—	Propionic acid	*Additive composition* Propionic acid ≥ 99,5 % *Characterisation of the active substance* Propionic acid ≥ 99,5 % $C_3H_6O_2$ CAS No: 79-09-4 Non-volatile residue ≤ 0,01 % when dried at 140 °C to constant weight Aldehydes ≤ 0,1 % expressed as formaldehyde Produced by *Lactobacillus buchneri* (NCIMB 40788) *Analytical method*[a] *For the determination of propionic acid in the additive:* Gas chromatography with flame ionisation detector *For the determination of propionic acid in premixtures, feed and forage:* Gas chromatography with flame ionisation detector	All animal species	—	—	—	1. The simultaneous use of other organic acids at the maximum permitted doses is contraindicated. 2. The additive shall be used in easy to ensile material[b]. 3. Simultaneous use with other sources of the active substance shall not exceed the authorised maximum content.	15 April 2024

a 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

b Easy to ensile forage: > 3 % soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp). Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 305/2014. (See end of Document for details)*

				chemical synthesis *Method of Analysis*[a] Quantification of propionic acid as total propionic acid in feed additive, premixtures, feedingstuffs: ion exclusion High Performance Liquid Chromatography with refractive index (HPLC-RI)			4. For safety: breathing protection, eye protection, gloves and protective clothing shall be used during handling.	
1k281	—	Sodium propionate		*Additive composition* Sodium propionate ≥ 98,5 % *Characterisation of the active substance* Sodium propronate ≥ 98,5 % $C_3H_5O_2Na$ CAS No: 137-40-6 Loss on	—	—	—	1. The simultaneous use of other organic acids at the maximum permitted doses is contraindicated. 2. additive shall be used in easy to ensile materials[b].	15 April 2024

a 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

b Easy to ensile forage: > 3 % soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp). Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).

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				drying ≤ 4 % determined by drying for two hours at 105 °C Water insoluble ≤ 0,1 % Produced by chemical synthesis *Method of Analysis*[a] Quantification of sodium propionate in feed additive: (1)	ion exclusion High Performance Liquid Chromatography with refractive index detection (HPLC-RI) — for the determination of total propionate; and (2) atomic absorption spectrometry,		3. Simultaneous use with other sources of the active substance shall not exceed the authorised maximum content. 4. For safety: breathing protection, eye protection, gloves and protective clothing shall be used during handling.	

a 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

b Easy to ensile forage: > 3 % soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp). Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).