Commission Implementing Regulation (EU) 2016/2023 of 18 November 2016 concerning the authorisation of sodium benzoate, potassium sorbate, formic acid and sodium formate as feed additives for all animal species (Text with EEA relevance)

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(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(7) of Regulation (EC) No 1831/2003 in conjunction with Article 10(1) to (4) thereof sets out specific provisions for the evaluation of products used in the Union as silage additives.

(2) In accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003, sodium benzoate was entered in the Register of Feed Additives as existing product belonging to the functional group of silage additives, for all animal species.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, application was submitted for the authorisation of sodium benzoate and in accordance with Article 7 of Regulation (EC) No 1831/2003 applications were submitted for the authorisations of potassium sorbate, formic acid and sodium formate. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) Those applications concern the authorisations of sodium benzoate, potassium sorbate, formic acid and sodium formate as feed additives for all animal species to be classified in the category ‘technological additives’.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 13 June 2012[(2)] that, under the proposed conditions of use, sodium benzoate does not have an adverse effect on animal health, human health or the environment; however it was considered as a potential sensitizer and a risk for inhalation cannot be excluded. The Authority also concluded that the additive has a potential to improve the production

of silage by reducing the pH and increasing the preservation of dry matter in easy, moderate difficult and difficult to ensile material.

(6) The Authority concluded in its opinion of 18 June 2013[(3)] that, under the proposed conditions of use, potassium sorbate does not have an adverse effect on animal health, human health or the environment; however it was considered irritant for skin and eyes and potential irritant to respiratory tract. The Authority also concluded that the additive has a potential to improve the aerobic stability of silage in easy and moderate difficult to ensile material.

(7) The Authority concluded in its opinion of 11 September 2014[(4)] that, under the proposed conditions of use, formic acid does not have an adverse effect on animal health, human health or the environment; however it was considered corrosive for skin and eyes and respiratory tract. The Authority also concluded that the additive has a potential to improve the ensiling process and the quality of the silage in aerobic stability of silage in easy, in moderate difficult and difficult to ensile material.

(8) The Authority concluded in its opinion of 11 March 2015[(5)] that, under the proposed conditions of use, sodium formate does not have an adverse effect on animal health, human health or the environment; however the liquid form was considered corrosive for skin and eyes and to respiratory tract. The Authority also concluded that the additive has a potential to improve the preservation of nutrients by reducing the dry matter loss in easy, moderate and difficult to ensile material.

(9) For sodium benzoate, potassium sorbate, formic acid and sodium formate, 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(10) The assessments of sodium benzoate, potassium sorbate, formic acid and sodium formate show that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those additives should be authorised as specified in the Annex to this Regulation.

(11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of sodium benzoate, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(12) 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

Authorisation

The additives 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

Transitional measures

The sodium benzoate specified in the Annex and feed containing it, which are produced and labelled before 9 June 2017 in accordance with the rules applicable before 9 December 2016 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 18 November 2016.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/2023. (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									
1k301	—	Sodium benzoate	*Additive composition* Sodium benzoate ≥ 99,5 % Solid form *Characterisation of the active substance* Sodium benzoate ≥ 99,5 % $C_7 H_5 Na O_2$ CAS no 532-32-1 Produced by chemical synthesis *Analytical method*[a] For the determination of sodium benzoate: titrimetric method (01/2008:0123 of	All animal species	—		2 400	1. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures	9 December 2026

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

b Easy to ensile forage: > 3 % soluble carbohydrates in fresh materials. Moderately difficult to ensile forage: 1,5-3,0 % soluble carbohydrates in fresh materials. 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) 2016/2023. (See end of Document for details)*

			European Pharmacopoeia).					and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves. 2. The mixture of different sources of sodium benzoate shall not exceed the permitted maximum contents.	
1k202	—	Potassium sorbate	*Additive composition* Potassium sorbate ≥ 99 % Solid form *Characterisation of the active substance* Potassium sorbate ≥ 99 %	All animal species			300	1. For users of the additive and premixtures, feed business operators shall establish operational procedures	9 December 2026

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

b Easy to ensile forage: > 3 % soluble carbohydrates in fresh materials. Moderately difficult to ensile forage: 1,5-3,0 % soluble carbohydrates in fresh materials. Commission Regulation (EC) No 429/2008 (OJ L 133, 22.5.2008, p. 1).