

COMMISSION IMPLEMENTING REGULATION (EU) 2018/982**of 11 July 2018****concerning the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as feed additive for chickens for fattening and chickens reared for laying (holder of the authorisation Novus Europe N.A./S.V.)****(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 the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for chickens for fattening, chickens reared for laying, minor avian species for fattening and reared for laying. 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 the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for chickens for fattening, chickens reared for laying, minor avian species for fattening and reared for laying, to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 2 December 2014 ⁽²⁾ and 28 September 2017 ⁽³⁾ that, under the proposed conditions of use, the preparation of benzoic acid, calcium formate and fumaric acid does not have an adverse effect on animal health, human health or the environment. The Authority also concluded that it has the potential to improve the performance of chickens for fattening and this conclusion can be extended to chickens reared for laying. However, since no conclusions can be drawn on the margin of safety of the additive for major target species, the conclusions on safety cannot be extrapolated to minor avian species for fattening and to minor avian species reared for laying. 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 benzoic acid, calcium formate and fumaric acid 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) 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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ *EFSA Journal* 2015;13(5):3794.

⁽³⁾ *EFSA Journal* 2017;15(10):5025.

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, 11 July 2018.

For the Commission
The President
Jean-Claude JUNCKER

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improving zootechnical performance)									
4d14	Novus Europe N.A./S.V.	Preparation of benzoic acid, calcium formate and fumaric acid	<p><i>Additive composition</i></p> <p>Preparation of benzoic acid, calcium formate and fumaric acid having a minimum content of:</p> <p>Benzoic acid: 42,5-50 %</p> <p>Calcium formate: 2,5-3,5 %</p> <p>Fumaric acid: 0,8-1,2 %</p> <p>Granulated form</p> <p><i>Characterisation of the active substance</i></p> <p>benzoic acid CAS number: 65-85-0 ($\geq 99,0$ % purity); $C_7H_6O_2$</p> <p>calcium formate: CAS number 544-17-2; $C_2H_2O_4Ca$;</p> <p>fumaric acid ($\geq 99,5$ % purity): CAS number 110-17-8; $C_4H_4O_4$.</p> <p><i>Analytical method</i> (1)</p> <p>For the determination of benzoic acid, calcium formate and fumaric acid in the feed additive:</p> <p>— high performance liquid chromatography with UV detection (HPLC-UV)</p>	Chickens for fattening Chickens reared for laying	—	500	1 000	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, 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, calcium formate or formate and fumaric acid. 3. 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 shall be used with personal protective equipment, including breathing protection. 	1 August 2028

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 additive/kg of complete feedingstuff with a moisture content of 12 %			
			<p>For the determination of total calcium in the feed additive:</p> <ul style="list-style-type: none"> — atomic absorption spectrometry (AAS) – EN ISO 6869; or — inductively coupled plasma atomic emission spectrometry (ICP-AES) – EN 15510 <p>For the determination of benzoic acid in premixtures and feedingstuffs:</p> <ul style="list-style-type: none"> — high performance liquid chromatography with UV detection (HPLC-UV) <p>For the determination of calcium formate and fumaric acid in premixtures:</p> <ul style="list-style-type: none"> — ion-exclusion high performance liquid chromatography with UV or refractive index detection (HPLC-UV/RI) 						

(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>