

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2097**of 29 November 2021****concerning the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for turkeys for fattening and turkeys reared for breeding (holder of the authorisation Novus Europe NV)****(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. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of benzoic acid, calcium formate and fumaric acid as a feed additive for turkeys for fattening and turkeys reared for breeding, to be classified in the additive category 'zootechnical additives', functional group 'other zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 March 2021 ⁽²⁾ 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, consumer safety or the environment. The Authority concluded that the additive presents a low inhalation risk for its users. 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. The Authority also concluded that the additive has the potential to improve the performance of turkeys for fattening and this conclusion can be extended to turkeys reared for breeding. 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 2021;19(4):6528.

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, 29 November 2021.

For the Commission
The President
Ursula VON DER LEYEN

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 feed with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improving zootechnical performance).									
4d14	Novus Europe NV	Preparation of benzoic acid, calcium formate and fumaric acid	Additive composition: Preparation of benzoic acid, calcium formate and fumaric acid having a minimum content of: benzoic acid: 42,5-50 %, calcium formate: 2,5-3,5 %, fumaric acid: 0,8-1,2 %; Granulated form	Turkeys for fattening Turkeys reared for breeding	-	500	1 000	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 formic acid 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 concern-	20 December 2031
			Characterisation of the active substance: Benzoic acid (purity ≥ 99,0 %); CAS number: 65-85-0; Chemical formula C ₇ H ₆ O ₂ Calcium formate: CAS number 544-17-2; Chemical formula C ₂ H ₂ O ₄ Ca; Fumaric acid (purity ≥ 99,5 %): CAS number 110-17-8; Chemical formula C ₄ H ₄ O ₄ .						
			Analytical method ⁽¹⁾ For the determination of benzoic acid, calcium formate and fumaric acid in the feed additive: — high performance liquid chromatography with UV detection (HPLC-UV);						

			For the determination of total calcium in the feed additive: — atomic absorption spectrometry (AAS) – EN ISO 6869; or — inductively coupled plasma atomic emission spectrometry (ICP-AES) – EN 15510; For the determination of benzoic acid in premixtures and feedingstuffs: — high performance liquid chromatography with UV detection (HPLC-UV); For the determination of calcium formate and fumaric acid in premixtures: — ion-exclusion high performance liquid chromatography with UV or refractive index detection (HPLC-UV/RI).					ing 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) 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>