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)

# 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<sup>(1)</sup>, 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<sup>(2)</sup> and 28 September 2017<sup>(3)</sup> 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.

#### 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

Identifica <b>Niom</b> e number of the		chemicalor				nurMaxim nt content		End nsf	
of the additive	holder e of authori	isation	descrip	calinimal	y	kg of	ure		period of authorisatio
					group:		otechnical a	additives	
(improv	ing zoote	chnical po	erformanc	e)					
<u>4</u> d14	Novus Europe N.A./ S.V.	<b>^</b>	ondditive composit Preparati of	Chickens (fror of attening Chickens reared for laying n Benzoic acid: 42,5-50 Calcium formate: 2,5-3,5 % Fumaric acid: 0,8-1,2 % ed erisation	~o	500	1 000	1.	1 August 28 directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. The additive shall not be used with other sources of
			of the active substanc	е					with other

**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

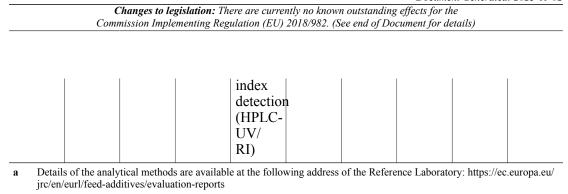
<b>Changes to legislation:</b> There are currently no known outstanding effects j	for the
Commission Implementing Regulation (EU) 2018/982. (See end of Document f	or details)

	purity); $C_7H_6O_2$ calcium formate: CAS number 544-17-2 $C_2H_2O_44$ fumaric acid ( $\geq 99,5$ purity): CAS number 110-17-8 $C_4H_4O_4$ . <i>Analytic</i> <i>method</i> <sup>a</sup> For the determin	Ca; % 3; <i>al</i>				3.	formate or formate and fumaric acid. For users of the additive and premixtures, feed business operators shall establish operational
	in the feed						their use.
	additive						Where
	_	high					those
		performa	ance				risks
		liquid	1				cannot
		chromate with	ograpny				be
		UV					eliminated
		detection	1				or
		(HPLC-	-				reduced to
		ÙV)					a
	For the						minimum
	determin	ation					by
	of total						such
	calcium						procedures
	in the						and
	feed						measures,
	additive						the
	<u> </u>	atomic absorptio	n				additive
		spectron					and
	,	<u>^</u>		64 7 6	<b>x</b> 1	1	premixtures
Details of the analytical meth	ods are availabl	e at the follow	ving address	of the Refere	nce Laborato	rv https://ec	europa eu/

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

	(AAS)	shall
	(AAS)	be
	EN	used
	ISO 6869;	with
	or	personal
	inductively	protective
	coupled	equipment,
	plasma	including
	atomic	breathing
	emission	protection.
	spectrometry	
	(ICP-	
	AES)	
	-	
	EN 15510	
For the		
	nination	
of		
benzoi		
acid in		
premix	xtures	
and		
feedin	gstuffs:	
	high	
	performance	
	liquid	
	chromatography	
	with	
	UV	
	detection	
	(HPLC-	
	UV)	
For the		
	nination	
of		
calcium		
format	e l	
and		
fumari		
acid in		
premix		
	ion-	
	exclusion	
	high	
	performance	
	liquid	
	chromatography	
	with	
	UV	
	or	
	refractive	
Details of the analytical methods are avail	able at the following address of the Reference	e Laboratory: https://ec.europa.eu/

**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



- (**1**) OJ L 268, 18.10.2003, p. 29.
- (2) *EFSA Journal* 2015;13(5):3794.
- (**3**) *EFSA Journal* 2017;15(10):5025.

**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/982.