Commission Implementing Regulation (EU) 2020/2119 of 16 December 2020 concerning the renewal of the authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for all porcine species (weaned), chickens for fattening, chickens reared for laying, all minor avian species for fattening and all minor avian species reared for laying and repealing Regulations (EU) No 1117/2010 and (EU) No 849/2012 (holder of authorisation Vetagro SpA) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2119

of 16 December 2020

concerning the renewal of the authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for all porcine species (weaned), chickens for fattening, chickens reared for laying, all minor avian species for fattening and all minor avian species reared for laying and repealing Regulations (EU) No 1117/2010 and (EU) No 849/2012 (holder of authorisation Vetagro SpA)

(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 and renewing such authorisation.

(2) The preparation of citric acid, sorbic acid, thymol and vanillin was authorised as a feed additive for 10 years for weaned piglets by Commission Regulation (EU) No 1117/2010[(2)] and for chickens for fattening, chickens reared for laying, all minor avian species for fattening and reared for laying and weaned suidae other than *Sus scrofa domesticus* by Commission Regulation (EU) No 849/2012[(3)].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin for all porcine species (weaned), chickens for fattening, chickens reared for laying, all minor avian species for fattening and reared for laying, requesting that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 17 March 2020[(4)] that, under the proposed conditions of use, the preparation of citric acid,

sorbic acid, thymol and vanillin does not have an adverse effect on animal health, consumer safety or the environment. The Authority also concluded that the additive is considered a potential skin and eyes irritant and a skin and respiratory sensitiser. 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.

(5) The assessment of the preparation of citric acid, sorbic acid, thymol and vanillin shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed.

(6) As a consequence of the renewal of the authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive, Regulations (EU) No 1117/2010 and (EU) No 849/2012 should be repealed.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) 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 authorisation of the preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, is renewed subject to the conditions laid down in that Annex.

Article 2

Regulations (EU) No 1117/2010 and (EU) No 849/2012 are repealed.

Article 3

The preparation of citric acid, sorbic acid, thymol and vanillin, as set out in Regulations (EU) No 1117/2010 and (EU) No 849/2012, premixtures and compound feed containing that additive, which are produced and labelled before 6 January 2021 in accordance with the rules applicable before 6 January 2021 may continue to be placed on the market and used until the existing stock are exhausted.

Article 4

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, 16 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/2119. (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 additive in complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters).									
4d3	Vetagro SpA	Preparation of protected citric acid, sorbic acid, thymol and vanillin	*Additive composition* Preparation of protected microbeads containing citric acid, sorbic acid, thymol and vanillin with a minimum of: Citric acid: 25 g/100 g Thymol: 1,7 g/100 g Sorbic acid: 16,7 g/100 g Vanillin: 1 g/100 g	Chickens for fattening Chickens reared for laying All minor avian species for fattening and reared for laying		200		1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The instructions of use shall include the following: 'The total maximum content by the different sources of citric acid and	6.1.2031
			Characterisation of active substance[a]	All porcine species (weaned)		1 000			

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