Commission Implementing Regulation (EU) 2020/1375 of 1 October 2020 concerning the authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for suckling piglets, turkeys for fattening and turkeys reared for breeding (holder of authorisation Vetagro SpA) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1375

of 1 October 2020

concerning the authorisation of the preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for suckling piglets, turkeys for fattening and turkeys reared for breeding (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 such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin. Those applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) Those applications concern the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for suckling piglets, turkeys for fattening and turkeys reared for breeding, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 4 July 2019[(2)] 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/eyes irritant and a skin 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. The Authority concluded that the additive has the potential to be efficacious in improving zootechnical performance in chickens for fattening and this conclusion can be extended to chickens reared for laying and to minor poultry species reared for laying[(3)]. Based on this, it its opinion of 2019 the Authority has extrapolated the conclusions reached

in chickens for fattening to turkeys for fattening and turkeys reared for breeding. It was also concluded that the additive has the potential to be efficacious in improving zootechnical performance in suckling piglets, at a recommended dose, by extending the conclusion reached in weaned piglets[4]. 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 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 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, 1 October 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) 2020/1375. (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 of additive/kg of 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	Suckling piglets		1 000		1. 2.	22.10.2030
			Characterisation of active substance: [a]	Turkeys for fattening Turkeys reared		200			

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. the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.
2. Indicate in the instruction of use: 'The total maximum content by the different sources of citric

			Citric acid $C_6H_8O_7$ (purity ≥ 99,5 %) 2-hydroxy-1,2,3-propanetricarboxylic acid, CAS number 77-92-9 anhydrous Sorbic acid $C_6H_8O_2$ (purity ≥ 99, 5 %) 2,4-hexadienoic acid, CAS number 110-44-1 Thymol (purity ≥ 98 %) 5-methyl-2-(1-methylethyl)phenol, CAS number 89-83-8) Vanillin (purity ≥ 99, 5 %) 4-hydroxy-3-methoxybenzaldehyde, CAS number 121-33-5)	for breeding				3.	acid and sorbic acid in complete feed shall not be exceeded’ For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such
			Analytical method[a]:						

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