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,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019;17(7):5795.
([3]) EFSA Journal 2012;10(5):2670.
([4]) EFSA Journal 2012;10(5):2670.

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

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 *Characterisation of active substance:* 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) *Analytical method* [1]: Determination of sorbic acid and thymol in feed additive, premixtures and feedingstuffs: — Reversed phase high performance liquid chromatography equipped with ultraviolet/diode array detection (RP-HPLC-UV/DAD)	Suckling piglets Turkeys for fattening Turkeys reared for breeding	- -	1 000 200	- -	1. In 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 acid and sorbic acid in complete feed shall not be exceeded' 3. 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 procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protection.	22.10.2030

			Determination of citric acid in the additive and premixtures: — Reversed phase high performance liquid chromatography equipped with ultraviolet/diode array detection (RP-HPLC-UV/DAD) Determination of citric acid in feedingstuffs: — enzymatic determination of citric acid content – NADH (reduced form of nicotinamide adenine dinucleotide) spectrometric method						

([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