COMMISSION REGULATION (EU) No 1117/2010

of 2 December 2010

concerning the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for weaned piglets (holder of the 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, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. The application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 25 May 2010 [2] that the preparation set out in the Annex, under the proposed conditions of use, do not have an adverse effect on animal health, human health or the environment, and that this additive has the potential to increase the growth rate and improve the feed to gain ratio of the target species. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this 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 the Food Chain and Animal Health,

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 20th day following 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, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] *EFSA Journal (2010); 8(6):1633.*

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 complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical parameters)									
4d 3	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 substances* 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 methods* (1) Determination of sorbic acid and thymol in feed: reverse phase high performance liquid chromatography method equipped with ultraviolet/diode array detection (RP-HPLC-UV/DAD). Determination of citric acid in the additive and premixtures: (RP-HPLC-UV/DAD). Determination of citric acid in feedingstuff: enzymatic determination of citric content-NADH (reduced form of nicotinamide adenine dinucleotide) spectrometric method.	Piglets (weaned)	—	1 000	—	1. For piglets (weaned) up to 35 kg. 2. For safety: breathing protection, glasses and gloves shall be used during handling.	23 December 2020

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives