Commission Implementing Regulation (EU) 2015/662 of 28 April 2015 concerning the authorisation of L-carnitine and L-carnitine L-tartrate as feed additives for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/662

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(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) L-carnitine and L-carnitine L-tartrate were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those products were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, two applications were submitted for the re-evaluation of L-carnitine and its preparations and L-carnitine L-tartrate for all animal species and, in accordance with Article 7 of that Regulation, for a new use in water for drinking. The applicants requested these additives to be classified in the additive category ‘nutritional additives’. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 24 April 2012[(3)] that, under the proposed conditions of use in feed and in water for drinking, L-carnitine and L-carnitine L-tartrate do not have adverse effects on animal or human health or the environment. The Authority concluded that L-carnitine and L-carnitine L-tartrate are regarded as effective sources of L-carnitine. The Authority further concluded that no safety concerns would arise for users. 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 additives in feed and in water submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of L-carnitine and L-carnitine L-tartrate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(7) 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 substances specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, are authorised as additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1 The substances specified in the Annex and premixtures containing those substances which are produced and labelled before 19 November 2015 in accordance with the rules applicable before 19 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 19 November 2015 in accordance with the rules applicable before 19 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food producing animals.

3 Compound feed and feed materials containing the substances specified in the Annex which are produced and labelled before 19 May 2017 in accordance with the rules applicable before 19 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 3

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, 28 April 2015.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/662. (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 active substance/kg of complete feedingstuff with a moisture content of 12 % or mg of the active substance/l of water			
Category of nutritional additives. Functional group: vitamins, provitamins and chemically well-defined substances having a similar effect									
3a910	—	L-carnitine	*Additive composition* L-carnitine *Active substance* L-carnitine $C_7H_{15}NO_3$ CAS No: 541-15-1 L-carnitine solid form produced by chemical synthesis: min. 97 %. *Method of Analysis*[a] For the determination of L-carnitine in the feed additive: titration	All animal species	—	—	—	1. L-carnitine may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixture, indicate the storage and stability conditions. 3. For safety: breathing protection,	19 May 2025

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

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			with perchloric acid (Ph Eur 6th edition, monograph 1339) For the determination of L-carnitine in premixtures: ion chromatography method with electrical conductivity detection (IC-ECD) or Spectrophotometric method after enzymatic reaction with carnitine-acetyl-transferase. For the determination of L-carnitine in feedingstuffs: Reversed Phase High Performance Liquid Chromatography (RP-HPLC) with fluorimetric detector or				safety glasses and gloves shall be worn during handling. 4. The additive may be used in water for drinking.	

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports