Commission Implementing Regulation (EU) 2016/1220 of 26 July 2016 concerning the authorisation of L-threonine produced by Escherichia coli as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1220

of 26 July 2016

concerning the authorisation of L-threonine produced by *Escherichia coli* as a feed additive for all animal species

(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 82/471/EEC[(2)].

(2) L-threonine was authorised without a time limit pursuant to Directive 82/471/EEC by Commission Directive 88/485/EEC[(3)] and was subsequently entered in the Register of feed additives as an existing product, 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, applications were submitted for the re-evaluation of L-threonine as feed additive for all animal species. Applications were also submitted for the authorisation of L-threonine for all animal species in accordance with Article 7 of that Regulation. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The applications concern the authorisation of L-threonine produced by *Escherichia coli* DSM 25086, *Escherichia coli* FERM BP-11383, *Escherichia coli* FERM BP-10942, *Escherichia coli* NRRL B-30843, *Escherichia coli* KCCM11133P, *Escherichia coli* DSM 25085, *Escherichia coli* CGMCC 3703 or *Escherichia coli* CGMCC 7.58 as a feed additive for all animal species, to be classified in the additive category ‘nutritional additives’.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 9 July 2013[(4)], 29 January 2014[(5)], 9 September 2014[(6)], 9 September 2015[(7)], 1 December 2015[(8)] and 19 April 2016[(9)] that, under the proposed conditions of use, L-threonine

produced by *Escherichia coli* DSM 25086, *Escherichia coli* FERM BP-11383, *Escherichia coli* FERM BP-10942, *Escherichia coli* NRRL B-30843, *Escherichia coli* KCCM11133P, *Escherichia coli* DSM 25085, *Escherichia coli* CGMCC 3703 and *Escherichia coli* CGMCC 7.58 does not have an adverse effect on animal health, human health or the environment, and that it is considered an efficacious source of the amino acid threonine for animal nutrition; for the supplemental L-threonine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. 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.

(6) The Authority expressed in its opinions a concern over the safety of L-threonine for the target species when administered via water for drinking. However, no maximum content for L-threonine is proposed by the Authority. Thus, it is in the case of administration of L-threonine via drinking water appropriate to alert the user to take into account the dietary supply with all the essential amino acids.

(7) The assessment of L-threonine 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 substance should be authorised as specified in the Annex to this Regulation.

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

(9) 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

Authorisation

The substance specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1 L-threonine authorised by Directive 88/485/EEC and premixtures containing it may be placed on the market until 16 May 2017 in accordance with the rules applicable before 16 August 2016 and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substance referred to in paragraph 1 may be placed on the market until 16 August 2017 in accordance with the rules applicable

before 16 August 2016 and used until the existing stocks are exhausted if they are intended for food producing animals.

3 Feed materials and compound feed containing the substance referred to in paragraph 1 may be placed on the market until 16 August 2018 in accordance with the rules applicable before 16 August 2016 and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 3

Entry into force

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, 26 July 2016.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2016/1220. (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 complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c410	—	L-threonine	*Additive composition:* Powder with a minimum of 98 % L-threonine (on a dry matter basis). *Characterisation of the active substance:* L-threonine produced by fermentation with *Escherichia coli* DSM 25086 or *Escherichia coli* FERM BP-11383 or *Escherichia coli* FERM BP-10942 or	All species	—	—	—	1. L-threonine may be placed on the market and used as an additive consisting of a preparation. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential	16.8.2026

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

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).