COMMISSION REGULATION (EU) No 348/2010

of 23 April 2010

concerning the authorisation of L-isoleucine 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.

(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 under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of L-isoleucine produced by *Escherichia coli* (FERM ABP-10641) as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 9 December 2009 [2] that L-isoleucine does not have an adverse effect on animal health, human health or the environment, and that this preparation can be considered a source of available isoleucine for all animal species. The Authority recommends appropriate measures for user safety. 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 L-isoleucine 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 additive 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 '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

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, 23 April 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] *The EFSA Journal* 2010; 8(1):1425.

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 nutritional additives. Functional group: amino acids, their salts and analogues									
3c3.8.1	—	L-isoleucine	Additive composition: L-isoleucine with a purity of at least 93,4 % (on dry matter) produced by *Escherichia coli* (FERM ABP-10641) ≤ 1 % unidentified impurities (as dry matter) Characterisation of the active substance: L-isoleucine ($C_6H_{13}NO_2$) Analytical method: Method for the determination of amino acids as set out in Commission Regulation (EC) No 152/2009 [1]	All animal species	—	—	—	1. The moisture content shall be indicated. 2. For safety reasons: breathing protection shall be used during handling.	14 May 2020

[1] OJ L 54, 26.2.2009, p. 1.