Commission Implementing Regulation (EU) 2020/1397 of 5 October 2020 concerning the renewal of the authorisation of L-isoleucine produced by Escherichia coli FERM ABP-10641 as a nutritional additive, its extension of use and the authorisation of L-isoleucine produced by Corynebacterium glutamicum KCCM 80189 as a feed additive for all animal species, and repealing Regulation (EU) No 348/2010 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1397

of 5 October 2020

concerning the renewal of the authorisation of L-isoleucine produced by *Escherichia coli* FERM ABP-10641 as a nutritional additive, its extension of use and the authorisation of L-isoleucine produced by *Corynebacterium glutamicum* KCCM 80189 as a feed additive for all animal species, and repealing Regulation (EU) No 348/2010

(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 and renewing such authorisation.

(2) L-isoleucine produced by *Escherichia coli* FERM ABP-10641 was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EU) No 348/2010[(2)].

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of L-isoleucine produced by *Escherichia coli* FERM ABP-10641 as a feed additive for all animal species, requesting this additive to be classified in the additive category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’. This application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003. Moreover, the application requested, in accordance with Article 7 of Regulation (EC) No 1831/2003, L-isoleucine produced by Escherichia coli FERM ABP-10641 to be authorised for use in water for drinking in the additive category ‘nutritional additives’, functional group ‘amino acids, their salts and analogues’ for all animal species, and for use in feed to be classified in the additive category ‘sensory additives’, functional group ‘flavouring compounds’. The application was accompanied

by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-isoleucine produced by *Corynebacterium glutamicum* KCCM 80 189 as a feed additive for use in feed and in water for drinking for all animal species. The application concerns the authorisation of L-isoleucine produced by *Corynebacterium glutamicum* KCCM 80 189 as a feed additive for all animal species to be classified in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in its opinions of 28 January 2020[(3)(4)] that, under the proposed conditions of use, L-isoleucine produced by *Escherichia coli* FERM ABP-10641 or *Corynebacterium glutamicum* KCCM 80 189 does not have an adverse effect on animal health, consumer health or the environment. It also stated that L-isoleucine produced by *Escherichia coli* FERM ABP-10641 was hazardous by inhalation for persons handling the additive. 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 this additive. No adverse effects on user safety were stated for L-isoleucine produced by *Corynebacterium glutamicum* KCCM 80 189. The Authority also concluded that the additive is an efficacious source of the essential amino acid isoleucine for non-ruminant animals and that for the supplemental L-isoleucine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority expressed concerns on the simultaneous oral administration of the amino acid via water for drinking and feed. However, the Authority did not propose a maximum content for L-isoleucine. Thus, in the case of supplementation with L-isoleucine via water for drinking, it is appropriate to alert the user to take into account the dietary supply with all the essential and conditionally essential amino acids.

(6) Restrictions and conditions should be provided for to allow for a better control for L-isoleucine when used as flavouring. For L-isoleucine used as flavouring, the recommended content should be indicated on the label. Where such content is exceeded, certain information should be indicated on the label of the additive and premixtures. As regards the use of L-isoleucine as a flavouring, the Authority states that no further demonstration of efficacy is necessary when the substance is used at the recommended dose level. The use of L-isoleucine as a flavouring compound is not authorised in water for drinking. The fact that the use of the L-isoleucine is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.

(7) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(8) The assessment of L-isoleucine produced by *Escherichia coli* FERM ABP-10641 and by *Corynebacterium glutamicum* KCCM 80 189 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.

(9) As a consequence of the renewal of the authorisation of L-isoleucine produced by *Escherichia coli* FERM ABP-10641 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EU) No 348/2010 should be repealed.

(10) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for L-isoleucine produced by *Escherichia coli* FERM ABP-10641, it is appropriate to provide a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(11) 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

1 The authorisation of L-isoleucine produced by *Escherichia coli* FERM ABP-10641, belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’, is renewed, extended to its use via water for drinking, subject to the conditions laid down in the Annex.

L-isoleucine produced by *Escherichia coli* FERM ABP-10641 belonging to the additive category ‘sensory additives’ and to the functional group ‘flavouring compounds’, is authorised as an additive in animal nutrition, subject to the conditions laid down in the Annex.

2 L-isoleucine produced by *Corynebacterium glutamicum* KCCM 80 189, 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 the Annex.

Article 2

1 L-isoleucine produced by *Escherichia coli* FERM ABP-10641 and premixtures containing it, which are produced and labelled before 26 April 2021 in accordance with the rules applicable before 26 October 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing L-isoleucine produced by *Escherichia coli* FERM ABP-10641 and premixtures containing it, which are produced and labelled before 26 October 2021 in accordance with the rules applicable before 26 October 2020 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 Feed materials and compound feed containing L-isoleucine produced by *Escherichia coli* FERM ABP-10641 and premixtures containing it, which are produced and labelled before 26 October 2022 in accordance with the rules applicable before 26 October 2020 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

Regulation (EU) No 348/2010 is repealed.

Article 4

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, 5 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1397. (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: nutritional additives. Functional group: amino acids, their salts and analogues.									
3c381		L-isoleucine	*Additive composition* Powder with a minimum content of L-isoleucine of 93,4 % (on a dry matter basis) *Characterisation of the active substance* L-isoleucine produced by fermentation with *Escherichia coli* FERM ABP-10641 IUPAC name: (2S,3S)-2-amino-3-methylpentanoic acid	All animal species				1. (3) Isoleucine 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, the storage conditions, the stability to heat	26 October 2030

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).

c Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2020;18(2):6022); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).