COMMISSION IMPLEMENTING REGULATION (EU) 2020/378

of 5 March 2020

concerning the authorisation of L-leucine 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(1) of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-leucine produced by *Escherichia coli* NITE BP-02351 as a nutritional feed additive for use in feed and in water for drinking and as sensory feed additive for use in feed for all animal species. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) This application concerns the authorisation of L-leucine produced by *Escherichia coli* NITE BP-02351 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') and in the additive category 'sensory additives' (functional group 'flavouring compounds').

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 ([2]) that, under the proposed conditions of use, L-leucine produced by *Escherichia coli* NITE BP-02351 does not have an adverse effect on animal health, consumer health or the environment. It also stated that L-leucine produced by *Escherichia coli* NITE BP-02351 could pose an inhalation risk for the users of the additive. Therefore, appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(5) The Authority concluded that it is an effective source of the amino acid L-leucine for all animal species. For the supplemental L-leucine to be fully efficacious in ruminants, it should be protected against degradation in the rumen. The Authority expressed in a previous statement a concern over potential nutritional imbalances for amino acids, when they are administered via water for drinking. However, the Authority did not propose a maximum content for L-leucine. Thus, it is appropriate to indicate on the label of the additive, and premixtures containing it, an alert to take into account the dietary supply with all the essential and conditionally essential amino acids, particularly in the case of supplementation with L-leucine as amino acid via water for drinking.

(6) As regards the use of L-leucine 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-leucine as a flavouring compound is not authorised in water for drinking. At the recommended dose, L-leucine as flavouring compound is not likely to pose any concern for the dietary supply with all the essential and conditionally essential amino acids.

(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.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) EFSA Journal 2019;17(5):5689.

(8) The assessment of L-leucine 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) The fact that the use of the L-leucine 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.

(10) 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

L-leucine produced by *Escherichia coli* NITE BP-02351, specified in the Annex, is authorised as a feed additive in animal nutrition in the additive category 'nutritional additives', functional group 'amino acids, their salts and analogues', and in the additive category 'sensory additives', functional group 'flavouring compounds', subject to the conditions laid down in that Annex.

Article 2

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 March 2020.

For the Commission
The President
Ursula VON DER LEYEN

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.									
3c382	-	L-leucine	**Additive composition:** Powder with a minimum content of L-leucine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water **Characterisation of the active substance:** L-leucine produced by fermentation with *Escherichia coli* NITE BP-02351. Chemical formula: C6H13NO2 CAS number: 61-90-5 **Analytical method** (1): For the identification of L-leucine in the feed additive: — Food Chemical Codex 'L-leucine monohydrochloride monograph' For the quantification of leucine in the feed additive: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) For the quantification of leucine in premixtures: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) or — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009	All animal species				1. L-leucine may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated. 4. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment, including breathing protection. 5. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air (2).	26.3.2030

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 %			
			For the quantification of leucine in compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009 For the quantification of leucine in water: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS)					6. Declaration to be made: 'The supplementation with L-leucine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances'.	
Category: Sensory additives. Functional group: Flavouring compounds									
3c382	-	L-leucine	**Additive composition:** Powder with a minimum content of L-leucine of 98 % (on a dry matter basis) and a maximum content of 1,5 % water **Characterisation of the active substance:** L-leucine produced by fermentation with *Escherichia coli* NITE BP-02351 Chemical formula: C6H13NO2 CAS number: 61-90-5 FLAVIS No 17.012	All animal species	-	-	-	1. L-leucine may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 4. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg.'	26.3.2030

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 %			
			Method of analysis (1): For the identification of L-leucine in the feed additive: — Food Chemical Codex 'L-leucine monohydrochloride monograph' For the quantification of leucine in the feed additive: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) For the quantification of leucine in premixtures: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) or — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Commission Regulation (EC) No 152/2009					5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg. 6. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment, including breathing protection. 7. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1600 IU endotoxins/m³ air (2).	

(1) 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

(2) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2019;17(5):5689); analytical method: European Pharmacopoeia 2.6.14 (bacterial endotoxins).