COMMISSION IMPLEMENTING REGULATION (EU) 2015/1114

of 9 July 2015

concerning the authorisation of L-valine produced by *Escherichia coli* as a feed additive for all animal species and amending Regulation (EC) No 403/2009 and Implementing Regulations (EU) No 848/2014 and (EU) No 1236/2014

(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) and Article 13(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 modifying such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 two applications were submitted for the authorisation of L-valine. These applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The applications concern the authorisation of L-valine produced by *Escherichia coli* NITE SD 00066 and L-valine produced by *Escherichia coli* NITE BP-01755 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 opinions of 9 December 2014 ([2]) and of 29 April 2015 ([3]) that, under the proposed conditions of use, the L-valine produced by *Escherichia coli* NITE SD 00066 and by *Escherichia coli* NITE BP-01755 does not have an adverse effect on animal health, human health or the environment and that it is considered an efficacious source of the essential amino acid L-valine for animal nutrition. 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.

(5) The assessment of that substance 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.

(6) Commission Regulation (EC) No 403/2009 ([4]), and Commission Implementing Regulations (EU) No 848/2014 ([5]) and (EU) No 1236/2014 ([6]) authorised L-valine as nutritional feed additive. In order to clarify that these additives have the same purity and do not contain residues of the producing microorganisms, their identification number should be harmonised even if they are produced from different microorganisms.

(7) As a consequence, the requirement to label L-valine in feed materials and compound feed together with the identification number is obsolete.

(8) Therefore, Regulation (EC) No 403/2009 and Implementing Regulations (EU) No 848/2014 and (EU) No 1236/2014 should be amended accordingly.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2015; 13(1):3965.
([3]) *EFSA Journal* 2015; 13(5):4110.
([4]) Commission Regulation (EC) No 403/2009 of 14 May 2009 concerning the authorisation of a preparation of L-valine as a feed additive (OJ L 120, 15.5.2009, p. 3).
([5]) Commission Implementing Regulation (EU) No 848/2014 of 4 August 2014 concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* as a feed additive for all animal species and amending Regulation (EC) No 403/2009 as regards the labelling of the feed additive L-valine (OJ L 232, 5.8.2014, p. 13).
([6]) Commission Implementing Regulation (EU) No 1236/2014 of 18 November 2014 concerning the authorisation of L-valine produced by *Corynebacterium glutamicum* (DSM 25202) as a feed additive for all animal species (OJ L 332, 19.11.2014, p. 26).

(9) 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.

(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

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

Amendments to Regulation (EC) No 403/2009

The Annex to Regulation (EC) No 403/2009 is amended as follows:

(1) in the first column, the text '3c3.7.1' is replaced by the text '3c370';

(2) in the ninth column, the second paragraph is deleted.

Article 3

Amendment to Implementing Regulation (EU) No 848/2014

In the ninth column of the Annex to Implementing Regulation (EU) No 848/2014, the second paragraph is deleted.

Article 4

Amendments to Implementing Regulation (EU) No 1236/2014

The Annex to Implementing Regulation (EU) No 1236/2014 is amended as follows:

(1) in the first column, the text '3c369' is replaced by the text '3c370';

(2) in the ninth column, the third paragraph is deleted.

Article 5

Transitional measures

1. L-valine authorised in Regulation (EC) No 403/2009 and Implementing Regulations (EU) No 848/2014 and (EU) No 1236/2014 and premixtures containing them, which are produced and labelled before 30 January 2016 in accordance with the rules applicable before 30 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substance specified in paragraph 1 which are produced and labelled before 30 July 2016 in accordance with the rules applicable before 30 July 2015 may continue to be placed on the market and used until the existing stocks are exhausted. As regards feed intended for non-food producing animals, the time period for production and labelling referred to in the first sentence shall end 30 July 2017.

Article 6

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, 9 July 2015.

For the Commission
The President
Jean-Claude JUNCKER

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									
3c370	—	L-valine	*Additive composition* L-valine minimum 98 % (on a dry matter basis) *Characterisation of the active substance* L-valine ((2S)-2-amino-3-methylbutanoic acid) produced by fermentation with *Escherichia coli* NITE SD 00066 or *Escherichia coli* NITE BP-01755 Chemical formula: $C_5H_{11}NO_2$ CAS number: 72-18-4 *Analytical method* (1) For the determination of L-valine in the feed additive: Food Chemical Codex 'L-valine monograph'. For the determination of valine in premixtures, compound feed and feed materials: Ion exchange chromatography coupled with post-column derivatisation and spectrophotometric detection (HPLC/VIS) — Commission Regulation (EC) No 152/2009 (2).	All species	—			1. The moisture content shall be indicated on the labelling. 2. For user safety: breathing protection, safety glasses and gloves shall be used during handling.	30 July 2025

(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) OJ L 54, 26.2.2009, p. 1.