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. (Solubility in water)	26 October 2030
								2. In the directions for use of the additive and premixture, the storage conditions, the stability to heat	

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).

			Chemical formula: $C_6H_{13}NO_2$ CAS number: 73-32-5						treatment and in water shall be indicated.
			Analytical method[a] For the identification of L-isoleucine in the feed additive: —	Food Chemical Codex ‘L-isoleucine monograph’				3. 4.	The additive may be used via water for drinking. Declaration to be made on the label of the additive and premixture:
			For the quantification of isoleucine in the feed additive: —	ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) or					— ‘The supplementation with L-isoleucine, in particular via water for drinking, shall take into account all essential and
			—	ion exchange chromatography					

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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).

				coupled with post-column derivatisation and photometric detection (IEC-VIS)					conditionally essential amino acids in order to avoid imbalances.’
			For the quantification of isoleucine 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)					— L-isoleucine content.
							5.	The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m^3 air [c].
							6.	For users of the additive and premixture, feed business operators shall

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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).

				No 152/2009[b] (Annex III, F)					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.
			For the quantification of isoleucine in compound feed and feed materials: —	ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Regulation (EC) No 152/2009 (Annex III, F)					
			For the quantification of isoleucine in water: —	ion exchange chromatography coupled with					

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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).

				post-column derivatisation and photometric detection (IEC-VIS)					
3c383		L-isoleucine	*Additive composition* Powder with a minimum content of L-isoleucine of 90 % *Characterisation of the active substance* L-isoleucine produced by fermentation with *Corynebacterium glutamicum* KCCM 80189 IUPAC name: (2S,3S)-2-amino-3-methylpentanoic acid Chemical formula: C6H13NO2 CAS number: 73-32-5 *Analytical method*[a]	All animal species			1. 26 October 2030 2.	1. L-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 treatment and in water

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).

			For the identification of L-isoleucine in the feed additive: — Food Chemical Codex ‘L-isoleucine monograph’ For the quantification of isoleucine in the feed additive: — 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						shall be indicated. 3. The additive may be used via water for drinking. 4. Declaration to be made on the label of the additive and premixture: — ‘The supplementation with L-isoleucine, in particular via water for drinking, shall take into account all essential and conditionally essential amino acids in

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).

				(IEC-VIS) For the quantification of isoleucine 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) – Regulation (EC) No 152/2009 (Annex III, F) For the quantification of					order to avoid imbalances.’ — L-isoleucine content.

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).

			isoleucine in compound feed and feed materials: —	ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) – Regulation (EC) No 152/2009 (Annex III, F)					
			For the quantification of isoleucine in water: —	ion exchange chromatography coupled with post-column derivatisation and photometric detection					

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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).

				(IEC-VIS)					
Category: Sensory additives. Functional group: Flavouring compounds									
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 Chemical formula: C6H13NO2 CAS number: 73-32-5 *Analytical method*[a]	All animal species				1. 26 October 2030 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	L-isoleucine may be placed on the market and used as an additive consisting of a preparation.

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).

			For the identification of L-isoleucine in the feed additive: — Food Chemical Codex ‘L-isoleucine monograph’ For the quantification of isoleucine in the feed additive: — 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					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.’ 5. The functional group, the identification number,	conditions and the stability to heat treatment shall be indicated.

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).

				(IEC-VIS) For the quantification of isoleucine 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) – Regulation (EC) No 152/2009 (Annex III, F))				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.	The endotoxin content of the

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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).

								7.	additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/ m^3 air[c]. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential by inhalation. Where those risks cannot be eliminated

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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).

									or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment.

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).

Changes to legislation:
There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1397, ANNEX.