

ANNEX

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisa- tion
					mg/kg of complete feed with 12 % moisture content			
Category: nutritional additives. Functional group: amino acids, their salts and analogues								
3c366	L-arginine	Additive composition: L-arginine ≥ 98,5% (on a dry matter basis) Solid form ----- Characterisation of the active substance: L-arginine ((S)-2-amino-5-guanidinopentanoic acid) produced with <i>Escherichia coli</i> CGMCC 7.401 Chemical formula: C ₆ H ₁₄ N ₄ O ₂ CAS number: 74–79-3 ----- Analytical method¹: For the identification of L-arginine in the feed additive: - Food Chemical Codex "L-arginine monograph" For the determination of arginine in the feed additive and water: - Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS);	All animal species	-	-	-	<div>1. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and in water shall be indicated.</div> <div>2. The additive may be used via water for drinking.</div> <div>3. Feed business operators shall ensure that L-arginine is rumen protected, when fed to ruminants.</div> <div>4. The moisture content shall be indicated on the label of the additive.</div> <div>5. The label of the additive and premixtures shall indicate the following: ‘The supplementation with L-arginine, in particular via water for drinking, shall take into account all essential and</div>	<div>[10 years from the date of entry into force of this Regulation. To be completed by the OP]</div>

¹ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

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		For the determination of arginine in premixtures and compound feed: - Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS), Commission Regulation (EC) 152/2009.					conditionally essential amino acids in order to avoid imbalances.’ 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	