

ANNEX

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Specie s or catego ry of animal	Maxi mum age	Minimum content	Maximu m content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a825iii	‘Riboflavin’ or ‘Vitamin B ₂ ’	Additive composition Riboflavin with a maximum of 1.5% of water Solid form Characterisation of active substance Riboflavin Chemical formula: C ₁₇ H ₂₀ N ₄ O ₆ CAS number: 83-88-5 Purity: minimum 98% Produced by fermentation with <i>Bacillus subtilis</i> CGMCC 7.449 Analytical method¹ – For the determination of riboflavin in the feed additive: European Pharmacopoeia monograph 0292 or High Performance Liquid Chromatography with UV detection, HPLC-UV (VDLUFA Bd. III, 13.9.1)	All animal species	-	-	-	1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water shall be indicated. 3. 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	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

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

Identification number of the 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 authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
		<div><div>– For the determination of riboflavin in the premixtures: High Performance Liquid Chromatography with UV detection, HPLC-UV (VDLUFA Bd. III, 13.9.1)</div><div>– -For the determination of riboflavin (as total vitamin B2) in compound feed and water: High Performance Liquid Chromatography with Fluorescence detection, HPLC-FLD (EN 14152)</div></div>					personal breathing, eye and skin protective equipment.	

Identification number of the 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 authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a825iv	‘Riboflavin’ or ‘Vitamin B ₂ ’	Additive composition Preparation containing a minimum of 80 % of riboflavin and a maximum of 3 % of water Solid form Characterisation of active substance Riboflavin Chemical formula: C ₁₇ H ₂₀ N ₄ O ₆ CAS number: 83-88-5	All animal species	-	-	-	1. The additive may be used via water for drinking. 2. In the directions for use of the additive and premixtures, the storage conditions, the stability to heat treatment and the stability in water shall be indicated. 3. For users of the additive and premixtures, feed business	[10 years from the date of entry into force of this Regulation. To be completed by the OP]

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Specie s or catego ry of animal	Maxi mum age	Minimum content	Maximu m content	Other provisions	End of period of authorisa- tion
					mg of active substance/kg of complete feedingstuff with a moisture content of 12%			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
		Purity: minimum 98% Produced by fermentation with <i>Bacillus subtilis</i> CGMCC 7.449 Analytical method² <ul style="list-style-type: none">For the determination of riboflavin in the feed additive and premixtures: High Performance Liquid Chromatography with UV detection, HPLC-UV (VDLUFA Bd. III, 13.9.1)For the determination of riboflavin (as total vitamin B₂) in compound feed and water: High Performance Liquid Chromatography with Fluorescence detection, HPLC-FLD (EN 14152)					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 breathing, eye and skin protective equipment.	

² 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_