ANNEX

Identi-fication 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 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								
3a880	Biotin	**Additive composition** Biotin **Characterisation of the active substance** D-(+)-biotin $C_{10}H_{16}N_2O_3S$ CAS number: 58-85-5 Biotin, solid form, produced by chemical synthesis Purity criteria: min. 97 % **Analytical method** [1] For the determination of D-(+)-biotin in feed additive: potentiometric titration assay and optical rotation identification (European Pharmacopeia monograph 1073). For the determination of Biotin in the feed additive, premixtures and compound feed: Reversed Phase High Performance Liquid Chromatography coupled to mass spectrometry (RP-HPLC-MS/MS).	All animal species	-	-	-	1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixtures shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 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 personal breathing protective equipment.	*[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

Identi-fication 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 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								
		For the determination of Biotin in water: microbiological assay (US Pharmacopoeia - Biotin assay/biological test).						

Identi-fication 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 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								
3a880i	Biotin	**Additive composition** Preparation containing 2% of biotin Solid form **Characterisation of the active substance** D-(+)-biotin $C_{10}H_{16}N_2O_3S$ CAS number: 58-85-5 Biotin, solid form, produced by chemical synthesis Purity criteria: min. 97 %	All animal species	-	-	-	1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixtures shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to	*[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	Species or categor y of animal	Maxim um age	Minimum content	Maximum 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								
		Analytical method [2] For the determination of D-(+)-biotin in feed additive: potentiometric titration assay and optical rotation identification (European Pharmacopeia monograph 1073). For the determination of Biotin in the feed additive, premixtures and compound feed: Reversed Phase High Performance Liquid Chromatography coupled to mass spectrometry (RP-HPLC-MS/MS). For the determination of Biotin in water: microbiological assay (US Pharmacopoeia - Biotin assay/biological test).					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 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_en

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or categor y of animal	Maxim um age	Minimum content	Maximum 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								
3a880ii	Biotin	**Additive composition** Preparation containing 10% of biotin Solid form **Characterisation of the active substance** D-(+)-biotin $C_{10}H_{16}N_2O_3S$ CAS number: 58-85-5 Biotin, solid form, produced by chemical synthesis Purity criteria: min. 97 % **Analytical method** [3] For the determination of D-(+)-biotin in feed additive: potentiometric titration assay and optical rotation identification (European Pharmacopeia monograph 1073). For the determination of Biotin in the feed additive, premixtures and compound feed: Reversed Phase High Performance Liquid Chromatography coupled to mass spectrometry (RP-HPLC-MS/MS).	All animal species	-	-	-	1. The additive may be used via water for drinking. 2. The directions for use of the additive and premixtures shall indicate the storage conditions, the stability to heat treatment and the stability in water for drinking. 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 personal breathing protective equipment.	*[10 years from the date of entry into force of this Regulation. To be completed by the OP]*

[3]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

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or categor y of animal	Maxim um age	Minimum content	Maximum 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								
		For the determination of Biotin in water: microbiological assay (US Pharmacopoeia - Biotin assay/biological test).						