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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1424

of 17 July 2025

concerning the renewal of the authorisation of biotin and two preparations of biotin as feed additives for all animal species and repealing Implementing Regulation (EU) 2015/723

(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) 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 renewing such authorisation.

(2) Biotin was authorised as a feed additive for all animal species as both a substance and as preparations for 10 years by Commission Implementing Regulation (EU) 2015/723 ([2]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of biotin and two preparations of biotin at concentrations of 2 % or 10 % for all animal species, requesting the additives to be classified in the additive category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 28 January 2025 ([3]) that under the conditions of use currently authorised biotin and the preparations of biotin at concentrations of 2 % or 10 % remain safe for all animal species, the consumers and the environment. The Authority further stated that biotin is not irritant to skin, eyes and is not a dermal sensitiser, and that exposure by inhalation is likely. The Authority stated that the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additives. Therefore, it concluded that there is no need for assessing the efficacy of the additives in the context of this renewal of the authorisation. The Authority considered that there is no need for specific requirements of post-market monitoring.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of biotin as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ([4]), an evaluation report of the Reference Laboratory is therefore not required.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) Commission Implementing Regulation (EU) 2015/723 of 5 May 2015 concerning the authorisation of biotin as a feed additive for all animal species (OJ L 115, 6.5.2015, p. 22, ELI: http://data.europa.eu/eli/reg_impl/2015/723/oj).
([3]) EFSA Journal. 2025;23:e9250. https://doi.org/10.2903/j.efsa.2025.9250.
([4]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additive (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

(6) Implementing Regulation (EU) 2015/723 provides that biotin is allowed to be placed on the market and used as an additive consisting of a preparation, but the composition of such preparation has erroneously not been specified in the terms of the authorisation. A more accurate description of biotin authorised as preparations at concentrations of 2 % or 10 % should be provided for, by specifying the composition of the additives authorised as preparations. A different identification number should also be assigned to distinguish between the three additives.

(7) In view of the above, the Commission considers that biotin and the preparations of biotin at concentrations of 2 % or 10 % satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of those additives should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(8) As a consequence of the renewal of the authorisation of biotin and the preparations of biotin at concentrations of 2 % or 10 %, Implementing Regulation (EU) 2015/723 should be repealed.

(9) Since the names of the additives have been modified, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of 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 authorisation of the substance and the preparations specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal

Implementing Regulation (EU) 2015/723 is repealed.

Article 3

Transitional measures

1. The feed additives biotin and its preparations as authorised by Implementing Regulation (EU) 2015/723 and premixtures containing those substances, which are produced and labelled before 7 February 2026 in accordance with the rules applicable before 7 August 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before 7 August 2026 in accordance with the rules applicable before 7 August 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before 7 August 2027 in accordance with the rules applicable before 7 August 2025 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

Article 4

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, 17 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

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								
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). For the determination of biotin in water: microbiological assay (US Pharmacopoeia – Biotin assay/biological test).	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.	7 August 2035

(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.

ELI: http://data.europa.eu/eli/reg_impl/2025/1424/oj

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								
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 % *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). For the determination of biotin in water: microbiological assay (US Pharmacopoeia – Biotin assay/biological test).	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.	7 August 2035

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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								
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* ([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). For the determination of Biotin in water: microbiological assay (US Pharmacopoeia – Biotin assay/biological test).	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.	7 August 2035

([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.

ELI: http://data.europa.eu/eli/reg_impl/2025/1424/oj