Commission Implementing Regulation (EU) 2015/723 of 5 May 2015 concerning the authorisation of biotin as a feed additive for all animal species (Text with EEA relevance)

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concerning the authorisation of biotin as a feed additive for all animal species

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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 such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Biotin was authorised without a time limit in accordance with Directive 70/524/EEC as feed additive on all animal species. This product was subsequently entered in the Register of feed additives as existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, two applications were submitted for the re-evaluation of biotin and preparations of biotin for all animal species and, in accordance with Article 7 of that Regulation, for a new use in water for drinking. The applicants requested these additives to be classified in the additive category ‘nutritional additives’. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 16 October 2012 and 17 October 2012[(3)] that under the proposed conditions of use in feed and water for drinking, biotin do not have adverse effects on animal health, human health or the environment. The Authority also concluded that synthetic biotin is regarded as an effective source of biotin in animal nutrition and that no safety concerns would arise for users. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed and water for drinking submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of biotin shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(7) 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

The substance 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 authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1 The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 26 November 2015 in accordance with the rules applicable before 26 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 26 November 2015 in accordance with the rules applicable before 26 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food producing animals.

3 Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 26 May 2017 in accordance with the rules applicable before 26 May 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 3

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, 5 May 2015.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/723. (See end of Document for details)*

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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 of active substance/kg of complete feedingstuff with a moisture content of 12 % or mg active substance/l of water.			
Category of nutritional additives. Functional group: vitamins, provitamins and chemically well defined substances having a similar effect									
3a880	—	Biotin	*Additive composition* Biotin *Active substance* D-(+)-biotin $C_{10}H_{16}N_2O_3S$ — — — *Method of Analysis*[a] For the determination of D-(+)-biotin in feed additive:	All animal species	—	—	—	1. Biotin 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, indicate the storage and stability conditions. 3. For safety: breathing protection shall be	26 May 2025

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports