EUROPEAN
COMMISSION

Brussels, XXX
SANTE/2171316/2025 CIS
(POOL/G5/2025/2171316/2171316-EN CIS.docx)
[…](2025) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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) No 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

---

1 OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

2 Commission Implementing Regulation (EU) No 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

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.

(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.

[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).

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 [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 [*24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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,

For the Commission
The President
Ursula VON DER LEYEN