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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

concerning the renewal of the authorisation of inositol as a feed additive for food-producing finfish, ornamental finfish, food-producing crustaceans and ornamental crustaceans and repealing Implementing Regulation (EU) No 1249/2014

(Text with EEA relevance)

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(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 nutrition¹, 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 an authorisation.
- (2) Inositol was authorised for a period of 10 years as a feed additive for fish and crustaceans by Commission Implementing Regulation (EU) No 1249/2014².
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of inositol as a feed additive for food-producing finfish, ornamental finfish, food-producing crustaceans and ornamental crustaceans, requesting the additive 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 16 September 2025³ that the applicant has provided evidence that inositol remains safe for food-producing finfish, ornamental finfish, food-producing crustaceans and ornamental crustaceans as well as for consumers, users and the environment under the conditions of use currently authorised. The Authority further stated that inositol is not irritant to skin and eyes and is not a skin sensitiser. 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

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>).

² Commission Implementing Regulation (EU) No 1249/2014 of 21 November 2014 concerning the authorisation of inositol as a feed additive for fish and crustaceans. (OJ L 335, 22.11.2014, p.7, ELI: http://data.europa.eu/eli/reg_impl/2014/1249/oj).

³ EFSA Journal. 2025;23:e9701, <https://doi.org/10.2903/j.efsa.2025.9701>.

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impact on the efficacy of the additive. Therefore, it concluded that there is no need for assessing the efficacy of the additive in the context of the 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 inositol 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 378/2005⁴, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that inositol satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed.
- (7) As a consequence of the renewal of the authorisation of inositol as a feed additive, Implementing Regulation (EU) No 1249/2014 should be repealed.
- (8) 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

Renewal of the authorisation

The authorisation of 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 renewed subject to the conditions laid down in that Annex.

Article 2

Repeal

Implementing Regulation (EU) No 1249/2014 is repealed.

Article 3

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.

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>).

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN