COMMISSION IMPLEMENTING REGULATION (EU) No 803/2013

of 22 August 2013

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

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

(2) Folic acid was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on all animal species as part of the group 'Vitamins, pro-vitamins and chemically well-defined substances having similar effect'. That product was subsequently entered in the European Union Register of Feed Additives as an 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, an application was submitted for the re-evaluation of folic acid, as a feed additive for all animal species, requesting that additive to be classified in the additive category 'nutritional additives'. That application was 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 opinion of 24 April 2012 ([3]) that, under the proposed conditions of use in feed, folic acid does not have an adverse effect on animal and consumer health, and it is not expected to pose additional risk for the environment. The Authority also concluded that no safety concerns would arise for users provided that appropriate protective measures are taken. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of folic acid shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that 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 the disposal of existing stocks of the additive, premixtures and compound feed containing it, as authorised by Directive 70/524/EEC.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation 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

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 12 March 2014 in accordance with the rules applicable before 12 September 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) *EFSA Journal 2012*; 10(5):2674.

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, 22 August 2013.

For the Commission
The President
José Manuel BARROSO

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/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									
3a316	—	Folic acid	*Additive composition* Preparation of folic acid, solid form *Characterisation of the active substance* Name: folic acid Chemical formula: $C_{19}H_{19}N_7O_6$ CAS No: 59-30-3 Produced by chemical synthesis Purity: not less than 96 % folic acid, anhydrous basis Purity criteria: as laid down by European Pharmacopeia 6th edition 01/2008/0067 *Method of Analysis* (1) — For the quantification of folic acid in feed additive and premixtures: Reverse Phase High-Performance Liquid Chromatography coupled to UV detection (RP-HPLC-UV). — For the quantification of total folates (including added folic acid) in feedingstuffs and water: microbiological assay — based on CEN-ring trial validated method EN 14131.	All animal species	—	—	—	1. If the preparation contains a technological additive or feed materials for which a maximum content is set or which is subject to other restrictions, the feed additive manufacturer shall provide this information to the customers. 2. In the directions for use of the additive and premixture, indicate the storage and stability conditions. 3. Folic acid may be used also via water for drinking. 4. For safety: breathing, eye and skin protection shall be used during handling.	12 September 2023

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx