Commission Implementing Regulation (EU) No 1078/2013 of 31 October 2013 concerning the authorisation of fumaric acid as a feed additive for all animal species (Text with EEA relevance)

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concerning the authorisation of fumaric acid 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) Fumaric acid was authorised in accordance with Directive 70/524/EEC as a feed additive, without a time limit, for use on all animal species by Commission Directive 80/678/EEC[(3)]. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of fumaric acid, as a feed additive for all animal species, requesting that additive to be classified in the additive category ‘technological 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 29 January 2013[(4)] that, under the proposed conditions of use, fumaric acid does not have an adverse effect on animal health, human health or the environment and it has the potential to preserve feed. 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1078/2013. (See end of Document for details)*

(5) The assessment of fumaric 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 fumaric acid 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The feed additive specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘preservatives’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

The feed additive specified in the Annex and feed containing that additive, which are produced and labelled before 21 May 2014 in accordance with the rules applicable before 21 November 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

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, 31 October 2013.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1078/2013. (See end of Document for details)*

ANNEX

Identification number of the additive	**Additive**	**Chemical formula, description, methods of analysis**	**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 technological additives. Functional group: preservatives								
1a297	Fumaric acid	*Additive composition* Fumaric acid 99,5 % Solid form *Characterisation of active substance* Fumaric acid $C_4H_4O_4$ CAS no 110-17-8 *Analytical method*[a] For the determination of fumaric acid in feed additive: infrared absorption spectrophotometry and titration with sodium hydroxide (Food Chemical	*Poultry and pigs* Young animals fed with milk replacers Other animal species	— — —	— — —	20 000 10 000[b] —	For safety: breathing protection, glasses and gloves shall be used during handling	21 November 2023

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/crl-feed-additives

b mg of fumaric acid per kg of milk replacer.