Commission Implementing Regulation (EU) 2020/1399 of 5 October 2020 concerning the authorisation of butylated hydroxyanisole as a feed additive for all animal species except cats (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1399

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concerning the authorisation of butylated hydroxyanisole as a feed additive for all animal species except cats

(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) Butylated hydroxyanisole was authorised without a time limit as a feed additive for all animal species in accordance with Council Directive 70/524/EEC. This additive was subsequently entered in the 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 butylated hydroxyanisole as a feed additive for all animal species. The applicant has later withdrawn the application with regard to cats.

(4) The applicant requested the additive to be classified in the additive category ‘technological additives’ and in the functional group ‘antioxidants’. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 6 March 2018[(3)] and 12 November 2019[(4)] that, under the proposed conditions of use, butylated hydroxyanisole does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive should be considered a skin, eye irritant and a potential skin sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also

concluded that since butylated hydroxyanisole is authorised as an antioxidant for use in food at comparable use levels, no studies are required to demonstrate the efficacy of butylated hydroxyanisole as an antioxidant in feedingstuffs for all animal species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

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

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

(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

Authorisation

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

Article 2

Transitional measures

1 The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 26 April 2021 in accordance with the rules applicable before 26 October 2020 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 as specified in the Annex which are produced and labelled before 26 October 2021 in accordance with the rules applicable before 26 October 2020 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 substances as specified in the Annex which are produced and labelled before 26 October 2022 in accordance with the rules applicable before 26 October 2020 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1399. (See end of Document for details)*

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.

Done at Brussels, 5 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1399. (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 moisturecontent of 12 %			
Category: Technological additives. Functional group: antioxidants								
1b320	Butylated hydroxyanisole	**Additive composition** Butylated hydroxyanisole (BHA) (≥98,5%) Waxy solid form	All animal species other than cats			150	1. In the directions for use of the additive and premixture, the storage conditions shall be indicated. 2. BHA can be used in combination with butylated hydroxytoluene (BHT) up to 150 mg of the mixture/ kg of complete feed. 3. For users	26.10.2030
		Characterisation of the active substance Mixture of: — 2-tert-butyl-4-hydroxyanisole — 3-tert-butyl-4-hydroxyanisole (≥85%) CAS No: 25013-16-5 $C_{11}H_{16}O_2$						
		Analytical method[a] For the quantification of BHA in the feed additive :						

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