

COMMISSION IMPLEMENTING REGULATION (EU) 2022/654
of 20 April 2022
concerning the authorisation of butylated hydroxyanisole as a feed additive for 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 Articles 9(2) and 10(5) 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. In particular, Article 10(2), in conjunction with Article 10(7) of that Regulation, provides for specific procedures for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾ and Council Directive 82/471/EEC ⁽³⁾.
- (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 has been 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 The applicant has later withdrawn the application with regard to cats, due to the adoption by EFSA on 12 November 2019 ⁽⁴⁾ of a non-favourable opinion concerning the safety of the additive for use for cats. The re-evaluation of butylated hydroxyanisole resulted in the authorisation thereof as a feed additive for all animal species except cats, by Commission Implementing Regulation (EU) 2020/1399 ⁽⁵⁾.
- (4) Article 10(5) of Regulation (EC) No 1831/2003 requires the adoption of a Regulation withdrawing from the market feed additives for which no application in accordance with Article 10(2) and (7) of that Regulation was submitted before the deadline set in those provisions, or for which an application was submitted but subsequently withdrawn.
- (5) Since the applicant has withdrawn the application with regard to cats, butylated hydroxyanisole (E 320) should be withdrawn from the market as a feed additive for cats.
- (6) In accordance with Article 7 of Regulation (EC) No 1831/2003, a new application was submitted for the authorisation of butylated hydroxyanisole as a feed additive for cats, to be classified in the category 'technological additives' and in the functional group 'antioxidants'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (OJ L 213, 21.7.1982, p. 8).

⁽⁴⁾ EFSA Journal 2019;17(12):5913.

⁽⁵⁾ 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 (OJ L 324, 6.10.2020, p. 29).

- (7) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 June 2021 ⁽⁶⁾ 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 as a skin and 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 feed for cats. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (8) 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.
- (9) As butylated hydroxyanisole as a feed additive for cats is ready to be newly authorised simultaneously to the adoption of a measure requiring a withdrawal from the market of the additive under the previous conditions of authorisation in accordance with Article 10(5) of Regulation (EC) No 1831/2003, such withdrawal from the market should not prevent the effective application of the new authorisation. The terms of the new authorisation differ from the previous ones in particular in that they provide for a more specific description of the additive and for the related methods of analysis, a new identification number of the additive and other provisions related to the directions of use and users' safety for the additive and premixture concerned.
- (10) Since there is no safety reason requiring the immediate withdrawal from the market of butylated hydroxyanisole as a feed additive for cats under the previous conditions of authorisation, it is appropriate to allow a limited transitional period for interested parties, within which existing stocks of butylated hydroxyanisole as a feed additive for cats, premixtures, feed materials and compound feed produced with that additive may be used up, in order to meet the new requirements resulting from the authorisation.
- (11) 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

Withdrawal from the market

Butylated hydroxyanisole (E 320) shall be withdrawn from the market as a feed additive for cats to the extent that it does not meet the conditions laid down in the authorisation referred to in Article 1.

⁽⁶⁾ EFSA Journal 2021;19(7):6714.

*Article 3***Transitional measures concerning the withdrawal from the market**

1. Butylated hydroxyanisole as a feed additive for cats and premixtures containing it, which are produced and labelled before 11 November 2022 in accordance with the rules applicable before 11 May 2022 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials intended for cats containing butylated hydroxyanisole, which are produced and labelled before 11 May 2023 in accordance with the rules applicable before 11 May 2022 may continue to be placed on the market and used until the existing stocks are exhausted.

*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, 20 April 2022.

For the Commission
The President
Ursula VON DER LEYEN

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: Technological additives. Functional group: antioxidants								
1b320	Butylated hydroxyanisole	<i>Additive composition</i> Butylated hydroxyanisole (BHA) (≥ 98,5 %) Waxy Solid form <i>Characterisation of the active substance</i> Mixture of: — 2-tert-butyl-4-hydroxyanisole — 3-tert-butyl-4-hydroxyanisole (≥ 85 %) CAS No: 25013-16-5 C ₁₁ H ₁₆ O ₂ <i>Analytical method ⁽¹⁾</i> For the quantification of BHA in the feed additive: — Gas Chromatography coupled to Flame Ionization Detection (GC-FID) (FCC7 method)	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 of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eye and breathing protection.	11 May 2032

		For the quantification of BHA in premixtures and feedingstuffs: — Reversed Phase High Performance Liquid Chromatography coupled to UltraViolet-Diode-Array Detection (RP-HPLC-UV-DAD, 285 nm)						
(4) 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								