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[...](2019) **XXX** draft

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

of **XXX**

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

(Text with EEA relevance)

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

of **XXX**

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 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 such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC².
- (2) Butylated hydroxyanisole was authorised without a time limit as a feed additive for all animal species in accordance with Directive 70/524/EEC³. 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 BHA 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 The applicant has later withdrawn the application with regard to cats.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 2018⁴ and 12 November 2018⁵ 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

¹ OJ L 268, 18.10.2003, p. 29.

² Fifteenth Commission Directive 76/603/EEC of 21 of 21 June 1976 amending the Annexes to the Council Directive of 23 November 1970 concerning additives in feedingstuffs (OJ L 198, 23.7.1976, p.10).

³ List of the authorised additives in feedingstuffs published in accordance with Article 9t (b) of Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁴ EFSA Journal 2018; 16(3):5215.

⁵ EFSA Journal 2019;17(12):5913.

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) 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
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,

For the Commission
The President
Ursula VON DER LEYEN