Commission Implementing Regulation (EU) 2020/173 of 6 February 2020 concerning the authorisation of brilliant blue FCF as a feed additive for cats and dogs (Text with EEA relevance)

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concerning the authorisation of brilliant blue FCF as a feed additive for cats and dogs

(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(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)]

(2) Brilliant blue FCF was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for dogs and cats belonging to the group ‘colourants, including pigments’, under the heading ‘colouring agents authorised for colouring foodstuffs by Community rules’. The 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 thereof, an application was submitted for the re-evaluation of brilliant blue FCF as a feed additive for dogs and cats. The applicant requested the additive to be classified in the additive category ‘sensory additive’ and in the functional group ‘colourants’. The 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 19 June 2013[(3)] that, under the proposed conditions of use, brilliant blue FCF does not have an adverse effect on animal health. It also concluded that the substance should be regarded as an inhalation hazard for the user of the additive and that in absence of data on skin and eye irritancy it could be considered as being potentially irritating to skin and/or eyes. 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. In accordance with Commission Regulation (EC) No 429/2008[(4)],

phase I of the environmental risk assessment has determined that Brilliant Blue FCF, as an additive intended for non-food producing animals, is exempted from further assessment due to the unlikelihood of a significant environmental effect, there being no scientifically-based evidence for concern having been identified by the Authority in its above-mentioned opinion. The Authority further concluded that the additive concerned is effective in adding colour to feedingstuffs. 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.

(5) The assessment of brilliant blue FCF 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 additive 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 of the substance concerned, 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 Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘colourants’, 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 that substance, which are produced and labelled before 27 August 2020 in accordance with the rules applicable before 27 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Feed materials and compound feed containing the substance specified in the Annex which are produced and labelled before 27 February 2022 in accordance with the rules applicable before 27 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/173. (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, 6 February 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) 2020/173. (See end of Document for details)*

ANNEX

Identification number of the additive	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 of active substance of kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants. (i) substances that add or restore colour in feedingstuffs								
2a133	Brilliant Blue FCF	**Additive composition:** Brilliant Blue FCF described as the sodium salt as the principal component. Solid form (powder) **Characterisation of the active substance as the sodium salt:** Disodium α-(4-(N-ethyl-3-sulphonatobenzylamino) phenyl)-α-(4-N-ethyl-3-sulphonatobenzylamino) cyclohexa-2,5-dienylidene) toluene-2-sulphonate The calcium and the	Cats	—	—	278	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures	27 February 2030
			Dogs	—	—	334		

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

		potassium salts are also permitted. Chemical formula: $C_{37}H_{34}N_2Na_2O_9S_3$ Solid form (powder) produced by chemical synthesis CAS number: 3844-45-9 Purity criteria Content not less than 85 % total colouring matters, calculated as the sodium salt (assay) Water insoluble matter: ≤ 0,2 % Subsidiary colouring matters: ≤ 6 % Organic compounds other than colouring matters: — Sum of 2-, 3- and 4-formyl					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 eye, skin and breathing protection.

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