Commission Implementing Regulation (EU) No 643/2013 of 4 July 2013 concerning the authorisation of Patent Blue V as a feed additive for non-food producing animals and amending Regulation (EC) No 358/2005 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 643/2013

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concerning the authorisation of Patent Blue V as a feed additive for non-food producing animals and amending Regulation (EC) No 358/2005

(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) Patent Blue V was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for certain feed materials on all animals and in feedingstuffs intended for cats and dogs by Commission Directive 74/181/EEC[(3)], and in feedingstuffs intended for use in grain eating ornamental birds and small rodents by Commission Regulation (EC) No 358/2005[(4)]. That product was subsequently entered in the European Union 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 Patent Blue V, as a feed additive for dogs, cats and other non-food producing animals, requesting that additive to be classified in the additive category ‘sensory 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 31 January 2013[(5)] that, under the proposed conditions of use in feed, Patent Blue V does not have an adverse effect on animal health, and it is not expected to pose additional risk for the environment. The Authority does not consider that there is a need for specific requirements of post-market monitoring. The Authority also concluded that no safety concerns would arise for users provided that appropriate protective measures are taken.

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 Patent Blue V 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 substance should be authorised as specified in the Annex to this Regulation.

(6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, Regulation (EC) No 358/2005 should therefore be amended accordingly.

(7) 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 the disposal of existing stocks of the additive, pre-mixtures and compound feed containing it, as authorised by Directive 74/181/EEC and Regulation (EC) No 358/2005.

(8) 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 substance specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘colorants, substances that add or restore colour in feedingstuffs’, is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

In Annex II to Regulation (EC) No 358/2005 the entry of the row E 131 is deleted.

Article 3

The substance specified in the Annex and feed containing that substance, which are produced and labelled before 25 July 2015 in accordance with the rules applicable before 25 July 2013, may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 4 July 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 643/2013. (See end of Document for details)*

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 643/2013. (See end of Document for details)*

ANNEX

Identification number of the additive	Name of the holder of authorisation	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/kg of complete feedingstuff with a moisture content of 12 %			
Category of sensory additives. Functional group: colorants, substances that add or restore colour in feedingstuffs									
2a131	—	Patent Blue V		*Active substance* Patent Blue V *Characterisation of the active substance* Name: calcium or sodium compound of [4-(α-(4-diethylaminophenyl)-5-hydroxy-2,4-disulfophenyl-methylidene) 2,5-cyclohexadien-1-ylidene] diethylammonium hydroxide inner salt and subsidiary colouring matters together with	—	—	250	For user safety: breathing protection, safety glasses and gloves should be worn during handling.	25 July 2023

a Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

b OJ L 6, 10.1.2009, p. 20.