COMMISSION IMPLEMENTING REGULATION (EU) No 868/2012

of 24 September 2012

concerning the authorisation of azorubine 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 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC [2].

(2) Azorubine (synonym carmoisine) was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on feed for cats and dogs falling under the category 'colouring agents' under the heading 'colouring agents authorised for colouring foodstuffs by Community rules, other than patent blue V, acid brilliant green BS and canthaxanthin'. That use was subsequently entered in the Community 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, an application was submitted for the re-evaluation of azorubine as a feed additive for cats and dogs, 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 2012 [3] that, under the proposed conditions of use, azorubine does not have an adverse effect on animal health, or the environment, and that it is effective as colourant. It concluded that no safety concerns would arise for users provided that appropriate protective measures are taken.. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of azorubine 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) Since modifications to the conditions of authorisation of azorubine are introduced and as there are no direct immediate effects on safety, a reasonable period should be allowed to elapse before authorisation in order to allow the interested parties to prepare themselves to meet the new requirements resulting from the authorisation. In addition, it is appropriate to allow a transitional period for the disposal of existing stocks of azorubine, as authorised in accordance with Directive 70/524/EEC and of feed containing azorubine.

(7) It is disproportionately complex for operators to adapt repeatedly and from one day to the other labels of feed containing different additives which have been successively authorised according to the procedure laid down in Article 10(2) of Regulation (EC) No 1831/2003 and for which new labelling rules are to be complied with. It is therefore appropriate to reduce the administrative burden on the operators by providing a period of time allowing a smooth conversion of labelling.

(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

Authorisation

The substance azorubine specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants', (i) 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

Labelling requirements

Feed containing azorubine shall be labelled in accordance with this Regulation at the latest by 25 May 2013.

However, feed containing azorubine which has been labelled in accordance with Directive 70/524/EEC before 25 May 2013 may continue to be placed on the market until stocks are exhausted.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 270, 14.12.1970, p. 1.
[3] *EFSA Journal 2012*; 10(2):2570.

Article 3

Transitional measures

Existing stocks of azorubine and of feed containing azorubine at the date of entry into force of this Regulation may continue to be placed on the market and used under the conditions of Directive 70/524/EEC until they are exhausted.

Article 4

Entry into force

This Regulation shall enter into force 25 November 2012.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 24 September 2012.

For the Commission
The President
José Manuel BARROSO

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of sensory additives. Functional group: colourants									
2a122	—	Azorubine or carmoisine	*Additive composition* Azorubine *Characterisation of the active substance* 1. Chemical name: Disodium 4-hydroxy-3-(4-sulfonato-1-naphthylazo) naphthalene-1-sulfonate 2. Synonyms: carmoisine, CI Food Red 3 3. Einecs: 222-657-4 4. Chemical formula: $C_{20}H_{12}N_2Na_2O_7S_2$ 5. Purity: 5.1. Assay: minimum contents of 85 % colouring matters calculated as the sodium salt 5.2. 4-aminonaphthalene-1-sulfonic acid and 4-hydroxynaphthalene-1-sulfonic acid: not more than 0,5 % 5.3. Subsidiary colouring matters: not more than 2,0 % 5.4. Water insoluble matter: not more than 0,2 % 5.5. Unsulfonated primary aromatic amines): not more than 0,01 % (calculated as aniline) 5.6. Ether extractable matter: not more than 0,2 % under neutral conditions	Cats and dogs	—	—	176	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For safety: breathing, eye and skin protection shall be used during handling.	25 November 2022

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 of active substance/kg of complete feedingstuff with a moisture content of 12 %			
			Method of Analysis (1) For the identification of azorubine in the feed additive: spectrophotometry at 516 nm in water and Thin Layer Chromatography (TLC) (FAO JECFA monographs No 1 (Vol. 4) Combined compendium for food additive specifications). For the determination of azorubine in the feed additive: spectrophotometry at 516 nm in aqueous solution Commission Directive 2008/128/EC (2).						

(1) 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
(2) OJ L 6, 10.1.2009, p. 20.