II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/228

of 19 February 2020

concerning the authorisation of erythrosine as a feed additive for dogs and 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 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) Erythrosine was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for ornamental fish belonging to the group 'colourants, including pigments', under the heading 'other colourants'. It was also authorised without a time limit 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 erythrosine as a feed additive for ornamental fish and for dogs and cats. The applicant requested the additive to be classified in the additive category 'sensory additive' and in the functional group 'colourants'. In accordance with Article 7 of Regulation (EC) No 1831/2003, the applicant also requested the authorisation of erythrosine as a feed additive for a new use in reptiles, to be classified in the additive category 'sensory additive' and in the functional group 'colourants'. Lately, the applicant withdrew the application for ornamental fish and for reptiles. 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 opinions of 16 November 2011 ([3]), 8 September 2015 ([4]) and 3 April 2019 ([5]) that, under the proposed conditions of use, erythrosine does not have an adverse effect on animal health. It also concluded that dermatological reactions, including photosensitivity, erythroderma and desquamation have been attributed to erythrosine and that an exposure of the lower respiratory tract is considered a hazard for the user of the additive. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users

([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]) EFSA Journal 2011;9(12):2447.
([4]) EFSA Journal 2015;13(9):4233.
([5]) EFSA Journal 2019;17(5):5699

of the additive. In accordance with Commission Regulation (EC) No 429/2008 [6], phase I of the environmental risk assessment has determined that erythrosine, 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 opinions. The Authority further concluded that the substance concerned is effective in adding colour to feedingstuffs and in favourably affecting the colour of ornamental fish. 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 the erythrosine 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 11 September 2020 in accordance with the rules applicable before 11 March 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 11 March 2022 in accordance with the rules applicable before 11 March 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

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, 19 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

[6] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

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								
2a127	Erythrosine	**Additive composition:** Erythrosine described as the sodium salt as the principal component. Solid form **Characterisation of the active substance as the sodium salt:** Erythrosine consists essentially of disodium 2-(2,4,5,7-tetraiodo-3- oxido-6-oxoxanthen-9-yl) benzoate monohydrate and subsidiary colouring matters together with water, sodium chloride and/or sodium sulphate as the principal uncoloured components. The calcium and the potassium salts are also permitted. Chemical formula: $C_{20}H_6I_4Na_2O_5 \cdot H_2O$ CAS number: 16423-68-0 Solid form produced by chemical synthesis. Purity criteria — Total colouring matters, calculated as the anhydrous sodium salt ≥ 87 % (assay) — Inorganic iodides ≤ 0,1 % (calculated as sodium iodide) — Water insoluble matter ≤ 0,2 % — Subsidiary colouring matters (except fluorescein) ≤ 4,0 % — Fluorescein ≤ 20 mg/kg — Organic compounds other than colouring matters: — Tri-iodoresorcinol ≤ 0,2 % — 2-(2,4-dihydroxy-3,5-diiodobenzoyl) benzoic acid ≤ 0,2 %	Dogs Cats	- -	- -	16 13	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 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 breathing protection.	11.3.2030

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 %			
		— Ether extractable matter from a solution of pH from 7 through 8 ≤ 0,2 %						
		Analytical method (1) For the quantification of erythrosine in the feed additive: — spectrophotometry at 526 nm (Commission Regulation (EU) No 231/2012 refers to FAO JECFA monographs n. 1 (Vol. 4)) For the quantification of erythrosine in feeding-stuffs: — high performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS)						

(1) 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