

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1712**of 7 September 2023****concerning the authorisation of Sunset Yellow FCF as a feed additive for cats, dogs, ornamental fish, grain-eating ornamental birds and small rodents****(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 an 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) Sunset Yellow FCF 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' and for dogs and cats under the heading 'other colourants – colouring agents authorised for colouring foodstuffs by Community rules'. Under the same Directive, it was authorised without a time limit for all species or categories of animals, with the exception of cats and dogs, in animal feedingstuffs only in products processed from: (i) waste products of foodstuffs; (ii) other base substances, with the exception of cereals and manioc flour, denaturated by means of these agents or coloured during technical preparation to ensure the necessary identification during manufacture. It was also authorised without a time limit for grain-eating ornamental birds and small rodents by Commission Regulation (EC) No 358/2005 ⁽³⁾. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1), point (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 Sunset Yellow FCF as a feed additive for dogs, cats, ornamental fish, grain-eating ornamental birds and small rodents. 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 23 March 2022 ⁽⁴⁾ that, under the proposed conditions of use, Sunset Yellow FCF does not have adverse effects on animal health. However, in the absence of adequate information, it could not conclude on the eyes and skin irritation potential, and on its skin sensitisation potential. Users are likely to be exposed by inhalation. In accordance with Commission Regulation (EC) No 429/2008 ⁽⁵⁾, phase I of the environmental risk assessment has determined that Sunset Yellow 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

⁽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⁾ Commission Regulation (EC) No 358/2005 of 2 March 2005 concerning the authorisations without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs (OJ L 57, 3.3.2005, p. 3).

⁽⁴⁾ EFSA Journal 2022;20(5):7266.

⁽⁵⁾ 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).

the Authority in its abovementioned opinion. The Authority could not conclude on the efficacy of Sunset Yellow FCF, considering the wide variety of feedingstuffs used in complete and complementary feed for the target species, and the uncertainty of which concentration of Sunset Yellow FCF would result in a visible effect. However, the Authority also stated that for this additive, which is authorised in food and, where the function for feed is the same as that for food, no further demonstration of efficacy might be necessary. The applicant also provided further information and the Commission considered that there is sufficient evidence of the efficacy of Sunset Yellow FCF. The Authority also verified the report on the methods 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 Sunset Yellow 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. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the additive, 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 28 March 2024, in accordance with the rules applicable before 28 September 2023, may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance as specified in the Annex, which are produced and labelled before 28 September 2025, in accordance with the rules applicable before 28 September 2023, 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, 7 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants. (i) substances that add or restore colour in feedingstuffs								
2a110	Sunset Yellow FCF	Additive composition	Cats	-	-	165	<div>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</div> <div>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 by such procedures and measures, the additive and premixtures shall be used with personal eyes, skin and breathing protective equipment.</div>	28 September 2033
		Sunset Yellow FCF	Dogs	-	-	198		
		Solid form (powder or granules)						
		Characterisation of the active substance	Ornamental fish	-	-	733		
		Sunset Yellow FCF, described as the sodium salt, consists essentially of disodium 2-hydroxy-1-(4-sulfonatophenylazo)naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components. Calcium and potassium salts are also allowed with the same characterisation as sodium salt. Produced by chemical synthesis Purity criteria: content not less than 90 % total colouring matters, calculated as the sodium salt (assay) Water insoluble matter: ≤ 0,2 % Subsidiary colouring matters: ≤ 5 % 1-(Phenylazo)-2-naphthalenol (Sudan I): ≤ 0,5 mg/kg Organic compounds other than colouring matters: ≤ 0,5 %	Grain-eating ornamental birds	-	-	24		
	Small rodents	-	-	750				

		<p>Unsulphonated primary aromatic amines: $\leq 0,01$ % (calculated as aniline) Ether extractable matter: $\leq 0,2$ % from a solution of pH 7</p> <p>Chemical formula: $C_{16}H_{10}N_2Na_2O_7S_2$ CAS number: 2783-94-0</p>						
		<p><i>Analytical method</i> ⁽¹⁾</p> <p>For the determination of the total colouring matters content of Sunset Yellow FCF in the feed additive:</p> <p>— spectrophotometry at 485 nm and titration with titan chloride as specified and described in Commission Regulation (EU) No 231/2012 ⁽²⁾ which refers to FAO JECFA Combined Compendium for Food Additive Specifications (Analytical methods Vol. 4) and the Monograph No 11 (2011) 'Sunset Yellow FCF'</p> <p>For the determination of Sunset Yellow FCF in compound feed:</p> <p>— high performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS)</p>						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

⁽²⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).