

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1486**of 2 September 2015****concerning the authorisation of canthaxanthin as feed additive for certain categories of poultry, ornamental fish and ornamental birds****(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) Canthaxanthin was authorised under Directive 70/524/EEC without a time limit for poultry and with a time limit for ornamental birds and ornamental fish. That product was subsequently entered in the 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 canthaxanthin and its preparations for certain categories of poultry (chickens and minor poultry species for fattening, laying poultry and poultry reared for laying), ornamental fish and ornamental birds and, in accordance with Article 7 of that Regulation, for a new use in water for drinking for all these species and categories. The applicant requested this additive to be classified in the additive category 'sensory additives', functional group 'colourants'. Those applications were 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 3 December 2013 ⁽³⁾ that, under the proposed conditions of use in feed, canthaxanthin does not have an adverse effect on animal health, human health or the environment. The Authority further concluded that no safety concerns would arise for users. The Authority concluded that canthaxanthin is efficacious in pigmenting egg yolk and skin/fat of poultry and has the potential to enhance plumage pigmentation of ornamental birds and the skin pigmentation 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of canthaxanthin shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation. Maximum contents should be set up for canthaxanthin. This additive may be used within a compound feed subsequently administered via water.
- (6) 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 interested parties to prepare themselves to meet 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,

⁽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 2014;12(1):3527.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants' is authorised as additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 23 March 2016 in accordance with the rules applicable before 23 September 2015 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 specified in the Annex which are produced and labelled before 23 September 2016 in accordance with the rules applicable before 23 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 23 September 2017 in accordance with the rules applicable before 23 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

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, 2 September 2015.

For the Commission

The President

Jean-Claude JUNKER

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	Maximum residue levels	End of period of authorisation
						mg of active substance/kg of complete feeding-stuff with a moisture content of 12 %				

Category of sensory additives. Functional group: Colourants
(ii) substances which, when fed to animals, add colours to food of animal origin

2a161g	—	Canthaxanthin	<i>Additive composition</i> Canthaxanthin. Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg. Dichloromethane ≤ 600 mg/kg <i>Characterisation of the active substance</i> — Canthaxanthin — C ₄₀ H ₅₂ O ₂ — CAS number: 514-78-3 — Canthaxanthin, solid form, produced by chemical synthesis. — Purity: Assay: min. 96 % Carotenoids other than canthaxanthin: not more than 5 % of total colouring matters. <i>Method of Analysis</i> ⁽¹⁾ 1. For the quantification of canthaxanthin in the feed additive: spectrophotometry at 426 nm. 2. For the quantification of canthaxanthin in the premixtures and feedingstuffs: Normal Phase High Performance Liquid Chromatography coupled to visible detection (NP-HPLC-VIS, 466 nm)	Chickens for fattening and minor poultry species for fattening.	—	—	25	1. Canthaxanthin may be placed on the market and used as an additive consisting of a preparation 2. The mixture of canthaxanthin with other carotenoids and xanthophylls shall not exceed 80 mg/kg of complete feed. 3. For safety: breathing protection, safety glasses and gloves should be worn during handling.	Poultry 15 mg canthaxanthin/kg liver (wet tissue) and 2,5 mg canthaxanthin/kg skin/fat (wet tissue) Laying poultry 30 mg canthaxanthin/kg egg yolk (wet tissue)	23.9.2025
				Laying poultry and poultry reared for laying.			8			

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

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	Maximum residue levels	End of period of authorisation
						mg of active substance/kg of complete feeding-stuff with a moisture content of 12 %				
Category of sensory additives. Functional group: Colourants										
(iii) substances which favourably affect the colour of ornamental fish or birds										
2a161g	—	Canthaxanthin	<i>Additive composition</i> Canthaxanthin. Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg Dichloromethane ≤ 600 mg/kg	Ornamental fish and ornamental birds except ornamental breeder hens.	—	—	100	1. Canthaxanthin may be placed on the market and used as an additive consisting of a preparation. 2. The mixture of canthaxanthin with other carotenoids and xanthopylls shall not exceed 100 mg/kg of complete feed. 3. For safety: breathing protection, safety glasses and gloves should be worn during handling.		23.9.2025
			<i>Characterisation of the active substance</i> — Canthaxanthin — C ₄₀ H ₅₂ O ₂ — CAS number: 514-78-3 — Canthaxanthin, solid form, produced by chemical synthesis. — Purity: Assay: min. 96 % Carotenoids other than canthaxanthin: not more than 5 % of total colouring matters. <i>Method of Analysis</i> ⁽¹⁾ For the quantification of canthaxanthin in the feed additive: spectrophotometry at 426 nm. For the quantification of canthaxanthin in the premixtures and feedingstuffs: Normal Phase High Performance Liquid Chromatography coupled to visible detection (NP-HPLC-VIS, 466 nm).	Ornamental breeder hens	—	—	8			

⁽¹⁾ Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>