Commission Implementing Regulation (EU) 2015/1415 of 20 August 2015 concerning the authorisation of astaxanthin as a feed additive for fish, crustaceans and ornamental fish (Text with EEA relevance)

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concerning the authorisation of astaxanthin as a feed additive for fish, crustaceans and ornamental fish

(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) Astaxanthin was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for salmon, trout 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, two applications were submitted for the re-evaluation of astaxanthin and its preparations as a sensory additive for salmon, trout and ornamental fish, and, in accordance with Article 7 of that Regulation, for a new use for crustaceans and for fish other than salmon and trout. The applicants requested this additive to be classified in the additive category '*sensory additives*'. 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 opinions of 20 May 2014[(3)] that, under the proposed conditions of use in feed, astaxanthin does not have an adverse effects on animal health, human health or the environment. The Authority also concluded that astaxanthin is efficacious in colouring the flesh of fish, the epidermis of crustaceans and the skin of ornamental fish. It further concluded that no safety concerns would arise for users. 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 astaxanthin 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 astaxanthin.

(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 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

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

1 The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 10 March 2016 in accordance with the rules applicable before 10 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 10 September 2016 in accordance with the rules applicable before 10 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for fish.

3 Compound feed and feed materials containing the substance specified in the Annex which are produced and labelled before 10 September 2017 in accordance with the rules applicable before 10 September 2015 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for ornamental fish.

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, 20 August 2015.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1415. (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 active substance of complete feedingstuff with a moisture content of 12 %			
Category of sensory additives. Functional group: a. colourants (ii) substances which, when fed to animals, add colours to food of animal origin									
2a161j	—	Astaxanthin	*Additive composition* Astaxanthin Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg Dichloromethane ≤ 600 mg/kg *Characterisation of the active substance* Astaxanthin $C_{40}H_{52}O_4$ CAS No: 7542-45-2 Astaxanthin, solid form, produced by chemical synthesis Purity criteria: — Assay (expressed as astaxanthin): min 96	Fish Crustaceans	—	—	100 100	1. Astaxanthin may be placed on the market and used as an additive consisting of a preparation. 2. In the directions for use of the additive and premixtures, indicate the stability and storage conditions. 3. The mixture of astaxanthin with other carotenoids	10 September 2025

a 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.

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				% of total colouring matters. — Carotenoids other than astaxanthin: max 5 % of total colouring matters. *Method of Analysis*[a] — For the quantification of Astaxanthin in the feed additive preparation: spectrophotometry at 431 nm. — For the quantification of Astaxanthin in the premixtures and feedingstuffs: Normal Phase High Performance Liquid Chromatography coupled to visible			and xanthophylls shall not exceed 100 mg/kg of complete feed (moisture content 12 %). 4. For safety: breathing protection, safety glasses and gloves shall be worn during handling.	

a 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.