Commission Implementing Regulation (EU) 2020/998 of 9 July 2020 concerning the renewal of the authorisation of astaxanthin-dimethyldisuccinate as a feed additive for fish and crustaceans and repealing Regulation (EC) No 393/2008 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/998

of 9 July 2020

concerning the renewal of the authorisation of astaxanthin-dimethyldisuccinate as a feed additive for fish and crustaceans and repealing Regulation (EC) No 393/2008

(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 and for the renewal of an authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.

(2) Astaxanthin-dimethyldisuccinate was authorised for 10 years as a feed additive for salmon and trout by Commission Regulation (EC) No 393/2008[(2)].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of astaxanthin-dimethyldisuccinate (the name of the additive changed from astaxanthin dimethyldisuccinate in the existing authorisation to astaxanthin-dimethyldisuccinate in the application, that is the correct name to refer to this additive) as a feed additive for salmon and trout, for a new use that extends the authorisation of astaxanthin dimethyldisuccinate as a feed additive for all fish and crustaceans according to Article 4(1) of that Regulation and for the modification of the existing conditions of authorisation of astaxanthin-dimethyldisuccinate as a feed additive to allow the use of the additive with no limitation of age or weight.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 November 2019[(3)] that, under the proposed conditions of use astaxanthin-dimethyldisuccinate, does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that there is no evidence that would lead to reconsider the previous conclusions as regards the users of the additive. No dermal or ocular risk for the users is likely to occur under practical conditions. In the absence of a toxicology study, it is not possible to establish a risk inhalation toxicity. Therefore, the

Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the health of users of the additive, including when it is used in the form of a preparation. The Authority further concluded that astaxanthin-dimethyldisuccinate is effective in adding colour to food of animal origin. 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 astaxanthin-dimethyldisuccinate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed and the terms of its authorisation modified as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of astaxanthin-dimethyldisuccinate as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 393/2008 should be repealed.

(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 authorisation of the additive specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘colourants: (ii) substances which, when fed to animals, add colours to food of animal origin’ for all salmon and trout species, is renewed and the terms of its authorisation are modified subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 393/2008 is repealed.

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, 9 July 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/998. (See end of Document for details)*

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. (ii) substances which, when fed to animals, add colours to food of animal origin								
2a165	Astaxanthin dimethyldisuccinate	*Additive composition* Astaxanthin-dimethyldisuccinate Triphenylphosphine oxide (TPPO) ≤ 100 mg/kg Dichloromethane ≤ 600 mg/kg *Characterisation of the active substance:* Astaxanthin-dimethyldisuccinate Chemical formula: $C_{50}H_{64}O_{10}$ Solid form produced by chemical synthesis. CAS number 578006-46-9 Purity criteria Astaxanthin-dimethyldisuccinate (all-E, 9-Z and 13-Z	Fish and crustaceans			138	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Astaxanthin-dimethyldisuccinate must be placed on the market and used as an additive consisting of	30.7.2030

a https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b 1,38 mg astaxanthin- dimethyldisuccinate is equivalent to 1 mg astaxanthin.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/998. (See end of Document for details)*

		isomers) ≥ 96 % Other carotenoids ≤ 4 % *Analytical method*[a] For the quantification of astaxanthin dimethyldisuccinate in the feed additive: —	spectrophotometry at 486 nm.					a preparation
		For the quantification of astaxanthin dimethyldisuccinate in the feed additive, premixtures and feedingstuffs: —	normal phase high performance liquid chromatography coupled to UV/VIS detection (HPLC-UV/VIS).				3.	If astaxanthin-dimethyldisuccinate is mixed with canthaxanthin and other astaxanthin sources, the total content of the mixture shall not exceed 100 mg astaxanthin equivalent[b]/kg in complete feedingstuffs.
							4.	For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential

a https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

b 1,38 mg astaxanthin- dimethyldisuccinate is equivalent to 1 mg astaxanthin.