COMMISSION IMPLEMENTING REGULATION (EU) 2020/1400

of 5 October 2020

concerning the authorisation of ethyl ester of β-apo-8'-carotenoic acid as a feed additive for chickens for fattening, laying hens and minor poultry species for laying and for fattening

(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]) and Article 4 of the same Regulation for the authorisation of a new use of an additive.

(2) Ethyl ester of β-apo-8'-carotenoic acid was authorised without a time limit in accordance with Directive 70/524/EEC as feed additive for poultry belonging to the functional group 'colourants, including pigments', under the heading 'carotenoids and xanthophylls'. 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 Articles 4 and 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of ethyl ester of β-apo-8'-carotenoic acid in water for drinking and the re-evaluation of ethyl ester of β-apo-8'-carotenoic acid as feed additive for chickens for fattening, laying hens and minor poultry species for laying and for fattening. The applicant requested the additive to be classified in the additive category 'sensory additives' 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 opinions of 8 March 2016 ([3]) and of 12 November 2019 ([4]) that, under the proposed conditions of use, ethyl ester of β-apo-8'-carotenoic acid does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that ethyl ester of β-apo-8'-carotenoic acid is not an irritant to skin and eyes, and not a dermal sensitiser. On the inhalation toxicity of ethyl ester of β-apo-8'-carotenoic acid, the Authority cannot conclude on the risk of users by inhalation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health. The Authority further concluded that the additive concerned 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 European Union Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) As regards the use in water for drinking, the Commission considers that the simultaneous use of the additive in water for drinking and feed is difficult to manage, as there are maximum levels established for safety reasons and there are also other additives containing xanthophylls and carotenoids that may be used in feed. The simultaneous use of ethyl ester of β-apo-8'-carotenoic acid in water for drinking and feed increases the ways of administration and the risk to exceed the maximum levels authorised for additives containing carotenoids and xanthophylls. Consequently, the use in water for drinking should be denied.

([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 2016;14(4):4439
([4]) EFSA Journal 2019;17(12):5911

(6) The assessment shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of ethyl ester of β-apo-8'-carotenoic acid should be authorised as specified in the Annex to this Regulation.

(7) 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.

(8) 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 a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

The authorised substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants', shall not be used in water for drinking.

Article 3

1 The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 26 April 2021 in accordance with the rules applicable before 26 October 2020 may continue to be placed on the market and used until 26 October 2021.

2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 26 October 2021 in accordance with the rules applicable before 26 October 2020 may continue to be placed on the market and used until 26 April 2022.

Article 4

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, 5 October 2020.

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	Maximum residue levels	Other provisions	End of period of authorisation
					mg of active substance / 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							
2a160f	Ethyl ester of β-apo-8'-carotenoic acid;	**Additive composition:** Ethyl ester of β-apo-8'-carotenoic acid. Triphenyl phosphine oxide (TPPO) ≤ 100 mg/kg.	Chickens for fattening and minor poultry for fattening.	-	-	15	— 20 mg ethyl ester of β-apo-8'-carotenoic acid /kg egg yolk (wet tissue). — 8 mg ethyl ester of β-apo-8'-carotenoic acid/kg liver (wet tissue). — 2.5 mg ethyl ester of β-apo-8'-carotenoic acid/kg skin/fat (wet tissue).	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment. shall be indi cated. 2. Ethyl ester of β-apo-8'-carotenoic acid shall be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business op erators shall establish opera tional procedures and organisa tional measures to address potential risks resulting from its use. Where those risks can not be eliminated or reduced to a minimum by such proce dures and measures, the addi tive and premixtures shall be used with personal protective equipment, including eye skin and breathing protection.	26.10.2030
		Characterisation of the active substance: Ethyl ester of β-apo-8'-carotenoic acid. Chemical formula: $C_{32}H_{44}O_2$ CAS number: 1109-11-1 Solid form produced by chemical synthesis. Purity criteria: ≥ 97% all isomers.	Laying hens and minor poultry for laying.	-	-	5			
		Analytical method — For the quantification of ethyl ester of β-apo-8'-carotenoic acid in the feed additive preparation: spectro photometry at 446 nm. — For the quantification of ethyl ester of β-apo-8'-carotenoic acid in the premixtures and feedingstuffs: Nor mal Phase High Performance Liquid Chromatography coupled to visible detection (NP-HPLC-VIS, 446 nm).		-	-				