COMMISSION IMPLEMENTING DECISION

of 22 January 2013

authorising the placing on the market of synthetic zeaxanthin as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2013) 110)

(Only the Dutch text is authentic)

(2013/49/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1], and in particular Article 7 thereof,

Whereas:

(1) On 1 June 2004, the company DSM Nutritional Products VML made a request to the competent authorities of the Netherlands to place synthetic zeaxanthin on the market as a novel food ingredient.

(2) On 16 June 2005 the competent food assessment body of the Netherlands issued its initial assessment report. In that report it came to the conclusion that synthetic zeaxanthin with a maximum intake for not more than 20 mg per person per day, would not present a significant risk for human health. However, it concluded that the data presented were not sufficient to complete the safety assessment.

(3) Therefore an additional assessment was required.

(4) The Commission forwarded the initial assessment report to all Member States on 1 August 2005 for additional comments.

(5) On 2 February 2007 the applicant informed the Commission that the use of zeaxanthin should be limited to be used only as an ingredient in food supplements.

(6) The Commission consulted the European Food Safety Authority (EFSA) on 20 March 2007.

(7) On 24 April 2008 the EFSA adopted a Scientific Opinion on the safety of 'synthetic zeaxanthin as an ingredient in food supplements' [2] concluding that based on the existing data, the safety of synthetic zeaxanthin as an ingredient in food supplements at the proposed level of 20 mg per person per day has not been established.

(8) On 25 January 2012 the applicant provided additional information and proposed an intake of synthetic zeaxanthin as an ingredient in food supplements of up to 2 mg per person per day.

(9) Following a request from the Commission, EFSA was asked to update its opinion on the safety of synthetic zeaxanthin as a novel food ingredient in food supplements in the light of the additional information. On 13 September 2012, EFSA adopted a 'Statement on the safety of synthetic zeaxanthin as an ingredient in food supplements' [3] concluding that the use level proposed by the applicant does not raise safety concerns.

(10) On the basis of the scientific assessment, it is established that synthetic zeaxanthin complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(11) The intentional addition of synthetic zeaxanthin to food for colouring purposes falls within the scope of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [4] and should be authorised in accordance with that Regulation.

(12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Synthetic zeaxanthin as specified in the Annex may be placed on the market in the Union as a novel food ingredient in food supplements at the maximum intake recommended by the manufacturer of up to 2 mg per day.

Article 2

The designation of synthetic zeaxanthin authorised by this Decision on the labelling of the foodstuffs containing it shall be 'synthetic zeaxanthin'.

[1] OJ L 43, 14.2.1997, p. 1.
[2] *EFSA Journal* (2008) 728, 1-27.
[3] *EFSA Journal* 2012: 10(10):2891.
[4] OJ L 354, 31.12.2008, p. 16.

Article 3

This Decision is addressed to DSM Nutritional Products, Alexander Fleminglaan 1, 2613 AX Delft, The Netherlands.

Done at Brussels, 22 January 2013.

For the Commission
Tonio BORG
Member of the Commission

ANNEX

SPECIFICATIONS OF SYNTHETIC ZEAXANTHIN

Definition

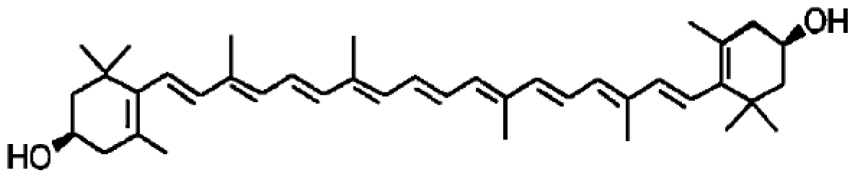
Zeaxanthin is a naturally occurring xanthophyll pigment, it is an oxygenated carotenoid. Synthetic zeaxanthin is produced by a multi-step chemical synthesis from smaller molecules.

Synthetic zeaxanthin is presented either as a spray-dried powder of gelatin or starch base ('beadlets') with added α-tocopherol and ascorbyl palmitate or as a corn oil suspension with added α-tocopherol

Description: Orange-red crystalline powder with little or no odour

Chemical formula: $C_{40}H_{56}O_2$

Structural formula:



CAS No: 144-68-3

Molecular weight: 568,9 daltons

Physical-chemical properties of synthetic zeaxanthin

Loss on drying	less than 0,2 %
All-trans zeaxanthin	more than 96 %
Cis-zeaxanthin	less than 2 %
Other carotenoids	less than 1,5 %
Triphenylphosphine oxid (CAS No 791-28-6)	less than 50 mg/kg