COMMISSION DECISION

of 30 April 2009

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

(notified under document number C(2009) 3149)

(Only the English text is authentic)

(2009/362/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 18 July 2008 the company DSM Nutritional Products Ltd. made a request to the competent authorities of Ireland to place synthetic lycopene on the market as a novel food ingredient; on 6 October 2008 the competent food assessment body of Ireland issued its initial assessment report. In that report it came to the conclusion that, in the light of other pending applications concerning lycopene, for synthetic lycopene an additional assessment is required in order to assure that an authorisation for use of the different lycopenes as novel food ingredients is granted under the same terms.

(2) The Commission forwarded the initial assessment report to all Member States on 22 October 2008.

(3) On 4 December 2008 EFSA adopted the 'Scientific Opinion of the Scientific Panel on dietetic Products, Nutrition and Allergies on a request from the Commission related to the safety of lycopene from *Blakeslea trispora* Cold Water Dispersion (CWD)'. This opinion came to the conclusions that lycopene preparations intended for use in foods and food supplements are formulated as suspensions in edible oils, direct compressible or water-dispersible powders. As lycopene may undergo oxidative changes in such formulations, sufficient antioxidative protection should be ascertained.

(4) EFSA also concluded that the consumption of lycopene by the average user will stay below the Acceptable Daily Intake (ADI), but that some users of lycopene may exceed the ADI. Therefore, it appears appropriate to collect intake data for a number of years following the authorisation in order to review this authorisation in the light of any further information on the safety of lycopene and its consumption. Particular attention should be given to the collection of data regarding levels of lycopene in breakfast cereals. However, this requirement under the present Decision, applies to the use of lycopene as a novel food ingredient and not to the use of lycopene as a food colour, that falls within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption [2].

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

(6) 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 lycopene, hereinafter called the product, as specified in Annex I may be placed on the market in the Community as a novel food ingredient to be used in the foods listed in Annex II.

Article 2

The designation of the novel food ingredient authorised by this Decision on the labelling of the foodstuff containing it shall be 'lycopene'.

Article 3

The company DSM Nutritional Products Ltd shall establish a monitoring programme accompanying the marketing of the product. This programme shall encompass information about use levels of lycopene in foods as specified in Annex III.

[1] OJ L 43, 14.2.1997, p. 1.

[2] OJ L 40, 11.2.1989, p. 27.

The data collected shall be made available to the Commission and Member States. In the light of new information and a report of EFSA, at the latest in the year 2014 the use of lycopene as an ingredient to foods shall be reviewed.

Article 4

This Decision is addressed to DSM Nutritional Products Ltd, Wurmis 576, CH – 4363 Kaiseraugst, Switzerland.

Done at Brussels, 30 April 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX I

Specifications of synthetic lycopene

DESCRIPTION

Synthetic lycopene is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists of ≥ 96 % lycopene and minor quantities of other related carotenoid components. Lycopene is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or red-violet. Antioxidative protection has to be assured.

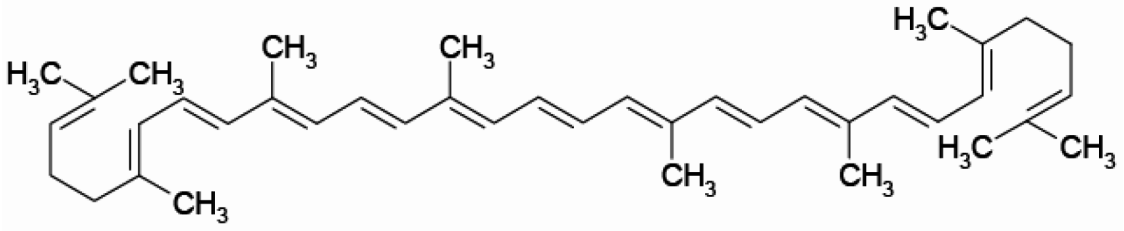
SPECIFICATION

Chemical name: Lycopene

C.A.S. number: 502-65-8 (all trans lycopene)

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

Structural formula:



Formula weight: 536,85

ANNEX II

List of foods to which synthetic lycopene may be added

Food category	Maximum content of lycopene
Fruit/vegetable juice-based drinks (including concentrates)	2,5 mg/100 g
Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g
Foods intended for use in energy-restricted diets for weight reduction	8 mg/meal replacement
Breakfast cereals	5 mg/100 g
Fats and dressings	10 mg/100 g
Soups other than tomato soups	1 mg/100 g
Bread (including crispy breads)	3 mg/100 g
Dietary foods for special medical purposes	In accordance with the particular nutritional requirements
Food supplements	15 mg per daily dose as recommended by the manufacturer

ANNEX III

Post launch monitoring of synthetic lycopene

INFORMATION TO BE COLLECTED

Quantities of synthetic lycopene provided by DSM Nutritional Products Ltd. to their customers for the production of final food products to be placed on the market in the European Union.

Results of data base searches on product launches of foods with added lycopene, including fortification levels and portion sizes per launched food by Member State.

REPORTING OF THE INFORMATION

The information above shall be reported to the European Commission annually for the years 2009 to 2012. For the first time on 31 October 2010 for the reporting period 1 July 2009 to 30 June 2010; and then with the same yearly reporting period for the following two years.

ADDITIONAL INFORMATION

Where appropriate and available to DSM Nutritional Products Ltd. also the same information on intakes of lycopene used as food colour should be reported.

Where available, DSM Nutritional Products Ltd. shall provide new scientific information for a reconsideration of the maximum safe intake levels of lycopene.

ASSESSMENT OF INTAKE LEVELS OF LYCOPENE

Based on the collected and reported information above, DSM Nutritional Products Ltd. shall carry out an updated intake assessment.

REVIEW

The Commission shall consult EFSA in 2013 to review the information provided by industry.