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## Statement on the post-marketing monitoring of the use of lycopene

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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## SCIENTIFIC OPINION

### Statement on the post-marketing monitoring of the use of lycopene<sup>1</sup>

#### EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide an update of its exposure assessment on lycopene as a novel food ingredient in the context of Regulation (EC) No 258/97 taking into account the new additional information from the post-marketing monitoring programme imposed by the Commission Decisions authorising the use of synthetic lycopene, lycopene oleoresin from tomatoes and lycopene from *Blakeslea trispora* as a novel food ingredient in several foodstuffs. The marketing authorisation holders for the use of lycopene as a novel food ingredient jointly prepared and submitted a dossier containing sales data, product launch data, an intake estimate and toxicological information. On the basis of information on sales and new product launch data for the period from July 2009 to June 2012 provided by the lycopene manufacturers, food supplements appear to be the main source of lycopene after intake from natural occurrence. Since no new toxicological studies became available, there is no scientific basis on which the ADI established by EFSA in 2008 could be reconsidered. On the basis of previous intake assessments performed by EFSA and data on sales and product launch data provided for the period from July 2009 to June 2012, the Panel concludes that intakes of naturally occurring lycopene and from its use as a food colouring and as a novel food ingredient at permitted use levels do not lead to intakes above the ADI of 0.5 mg/kg bw/day.

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#### KEY WORDS

lycopene, novel food ingredient, post-marketing monitoring

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## SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide an update of its exposure assessment on lycopene as a novel food ingredient in the context of Regulation (EC) No 258/97 taking into account the new additional information from the post-marketing monitoring programme imposed by the Commission Decisions authorising the use of synthetic lycopene (Decisions 2009/348/EC and 2009/362/EC), lycopene oleoresin from tomatoes (Decision 2009/355/EC) and lycopene from *Blakeslea trispora* (Decision 2009/365/EC) as a novel food ingredient (NFI) in several foodstuffs.

In 2008, EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) assessed the safety of lycopene from *B. trispora* as a food colouring in the food categories and at the use levels proposed by an applicant. The AFC Panel concluded that high intake estimates of lycopene, mainly from non-alcoholic, flavoured beverages, by pre-school and school children may exceed the Acceptable Daily Intake (ADI) of 0.5 mg/kg body weight (bw) per day established by the Panel. Intake of lycopene as a NFI was not considered by the AFC Panel in the intake assessment.

In its assessment of three novel food applications related to synthetic lycopene, lycopene oleoresin from tomatoes and cold water-dispersible lycopene products from *B. trispora*, the NDA Panel took into account lycopene intakes from natural occurrence, from its use as a food colouring and when used as a NFI in accordance with the intended uses and use levels as proposed in the three applications. High percentile lycopene intakes from natural sources, food colourings and NFIs were summed up to derive a high intake scenario. In its three opinions on lycopene as a NFI, the NDA Panel concluded that, for the average user, consumption of lycopene as a NFI and from all other sources would be below the ADI, but that some consumers of all considered age groups might exceed the ADI of 0.5 mg/kg bw/day.

In 2010, following a request from the European Commission, the EFSA Panel on Food Additives and Nutrient Sources (ANS) carried out a revised exposure assessment for children and adults (EFSA, 2010). EFSA should take into account the exposure to lycopene from natural occurrence and from its use as a food colouring at revised proposed maximum and typical use levels according to a range of scenarios defined in the terms of reference. The Commission asked EFSA to consider six different exposure scenarios: dietary intake of lycopene from natural occurrence, dietary intake from natural sources and colouring uses excluding all non-alcoholic, flavoured drinks, dietary intake from natural occurrence (5 mg/L) and colouring uses (12 mg/L) including selected non-alcoholic, flavoured drinks and the last two scenarios plus dietary intakes of lycopene as a NFI by considering the maximum content of lycopene for food categories. The ANS Panel concluded that only in the two scenarios when exposure to lycopene from its use as a NFI were also taken into account did the total exposure exceeded the ADI in all population groups studied. The ANS Panel noted that these estimates were based on several conservative assumptions and might overestimate the potential intake.

As a consequence, the Commission Decisions authorising the use of lycopene as a NFI imposed authorisation holders to collect information for the period from 1 July 2009 to 30 June 2012 on the quantities of lycopene sold to producers of final food products. In addition, authorisation holders should provide an updated intake assessment and, if available, new scientific information for a reconsideration of the maximum safe intake levels of lycopene. According to these Commission Decisions, the Commission shall consult EFSA to review the information provided by industry.

The marketing authorisation holders for the use of lycopene as a NFI jointly prepared and submitted a dossier which was forwarded by the European Commission to EFSA. The dossier contains sales data, product launch data, an intake estimate conducted by the manufacturers and toxicological information.

The total amounts of lycopene sold within these three years, from mid-2009 to mid-2012, were low. The manufacturers of lycopene also provided information on new lycopene product launches derived from query of the Mintel Group's Global New Products Database (GNPD) to characterise the

lycopene market for each of these three years, and also an update for 2013. The information from this research indicates that most uses of lycopene concerned food supplements. Very few food products from each of the food categories, non-alcoholic beverages, chewing gum, prepared meal, meal replacements, bakery and dairy products chocolate confectionery and meat substitute, also contained added lycopene. The information derived from the GNPD indicates that lycopene used as a NFI in food supplements is, for the most part, marketed with recommend dose levels between 1 and 10 mg lycopene per day, which is below maximum levels (15 mg per day) considered by the NDA Panel in its intake estimates in 2008. The GNPD also indicated that a few food supplements are marketed with recommended daily doses between 20 and 30 mg, which are above the level authorised by the European Commission of 15 mg per day.

On the basis of information on sales and new product launch data for the period from July 2009 to June 2012 provided by the lycopene manufacturers, food supplements appear to be the main source of lycopene after intake from natural occurrence.

The Panel considers that data provided by the manufacturers indicate that actual intakes of lycopene are below the estimates for lycopene (which are overestimations, because they considered that lycopene would be added to all permitted food categories at maximum permitted levels).

Since no new toxicological studies became available, there is no scientific basis on which the ADI established by EFSA in 2008 could be reconsidered.

On the basis of previous intake assessments performed by EFSA and data on sales and product launch data provided for the period from July 2009 to June 2012, the Panel concludes that intakes of naturally occurring lycopene and from its use as a food colouring and as a Novel Food Ingredient at permitted use levels do not lead to intakes above the ADI of 0.5 mg/kg bw/day.

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## **BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

In the past EFSA has adopted three scientific opinions regarding lycopene as a novel food ingredient. These opinions concern synthetic lycopene (adopted on 10 April 2008), lycopene oleoresin from tomatoes (adopted on 24 April 2008) and lycopene from *Blakeslea (B.) trispora* (adopted on 4 December 2008).

On the basis of these opinions, the Commission authorised the use of synthetic lycopene (Decisions 2009/348/EC and 2009/362/EC), lycopene oleoresin from tomatoes (Decision 2009/355/EC) and lycopene from *B. trispora* (Decision 2009/365/EC) as a novel food ingredient in several foodstuffs. However, the authorisations included the requirement to establish a monitoring programme to collect information on the use of lycopene in view to review the authorisation on the safety of lycopene and its consumption.

This information has been provided by three companies DSM Nutritional Products, LycoRed and BASF. Therefore, the Commission requests EFSA to provide an exposure assessment in view to review the authorisations.

## **TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide an exposure assessment of lycopene as a novel food ingredient in the context of Regulation (EC) No 258/97 taking into account the new additional information.

## ASSESSMENT

### 1. Introduction

Following a request from the European Commission, the European Food Safety Authority (EFSA) Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) was asked to evaluate the safety of use of lycopene from *Blakeslea trispora* as a food colouring in the food categories and at the use levels proposed by the applicant (EFSA, 2008a). In that opinion, the AFC Panel estimated that the mean total daily exposure to lycopene from *B. trispora* as a food colouring could potentially range from 2 (female adults) to 6 mg/day (pre-school children) and up to 11 (female adults) to 23 mg/day (pre-school children) at the 97.5<sup>th</sup> percentile (EFSA, 2008a). Non-alcoholic, flavoured drinks were found to be by far the largest potential source in all population groups considered, contributing to intakes from 66 % in male adults to more than 90 % in pre-school children. Taking into account that high consumption of fruits and vegetables, especially tomato products, might result in occasional intakes of 20 mg lycopene/day or more, the AFC Panel noted that an occasional combined high exposure from both natural dietary sources and food colourings up to 43 mg of lycopene per day cannot be excluded. The AFC Panel concluded that the 97.5<sup>th</sup> percentile intake of lycopene by adults from natural sources and as a food colouring would be expected to remain within the Acceptable Daily Intake (ADI) of 0.5 mg/kg body weight (bw) per day derived by the AFC Panel (EFSA, 2008a). However, the AFC Panel also considered that this would not hold for the high level intakes by pre-school and school children. Intake of lycopene as a novel food ingredient (NFI) was not considered by the AFC Panel in the intake assessment.

In 2008, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) assessed three novel food applications related to lycopene: synthetic lycopene (BASF), lycopene oleoresin from tomatoes (LycRed) and cold water-dispersible lycopene products from *B. trispora* (DSM) (EFSA, 2008b, c, d). In these opinions, the NDA Panel took into account lycopene intakes from natural sources and from use as a food colouring as estimated by the AFC Panel, plus estimated intakes of lycopene when used as a NFI according to the intended uses and at the use levels proposed in the three applications. High percentile lycopene intakes from natural sources, food colourings and NFIs were summed up to derive a high intake scenario. The Panel noted that the intake estimates were based on conservative assumptions. In its three opinions on lycopene as a NFI, the NDA Panel concluded that for the average user, consumption of lycopene as a NFI and from all other sources would be below the ADI, but that some consumers of all considered age groups might exceed the ADI of 0.5 mg/kg bw/day.

In 2010, following a request from the European Commission, the EFSA Panel on Food Additives and Nutrient Sources (ANS) carried out a revised exposure assessment for children and adults (EFSA, 2010). EFSA should take into account the exposure to lycopene from natural occurrence and from its use as a food colouring at revised proposed maximum and typical use levels according to a range of scenarios defined in the terms of reference. The Commission asked EFSA to consider six exposure scenarios:

- (1) dietary intake of lycopene from only natural occurrence;
- (2) dietary intake of lycopene from natural sources and colouring uses excluding all non-alcoholic, flavoured drinks;
- (3) dietary intake of lycopene from natural occurrence (5 mg/L) including selected non-alcoholic, flavoured drinks (ignoring dilutables and drinks that could never contain red colouring, such as colas, clear drinks and blackcurrant flavours, fruit juices and nectars);
- (4) dietary intake of lycopene from colouring uses (12 mg/L) including selected non-alcoholic, flavoured drinks (ignoring dilutables and drinks that could never contain red colouring, such as colas, clear drinks and blackcurrant flavours, fruit juices and nectars);
- (5) dietary intake of lycopene from natural sources (5 mg/L) including selected non-alcoholic, flavoured drinks (ignoring dilutables and drinks that could never contain red colouring, such

as colas, clear drinks and blackcurrant flavours, fruit juices and nectars) plus dietary intakes of lycopene as a NFI by considering the maximum content of lycopene for food categories specified in Table 1;

- (6) dietary intake of lycopene from colouring uses (12 mg/L) including selected non-alcoholic, flavoured drinks (ignoring dilutables and drinks that could never contain red colouring, such as colas, clear drinks and blackcurrant flavours, fruit juices and nectars) plus dietary intakes of lycopene as a NFI by considering the maximum content of lycopene for food categories specified in Table 1.

**Table 1:** List of foods to which lycopene may be added as a novel food ingredient according to Decisions 2009/348/EC, 2009/362/EC, 2009/355/EC and 2009/365/EC

Food category <sup>(a)</sup>	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
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 manufactures

(a): In addition to these food categories provided by the Commission in its mandate addressed to the ANS Panel in 2010, the Commission Decisions authorising the placing on the market of lycopene as a NFI under Regulation (EC) No 258/97 (Decisions 2009/348/EC, 2009/362/EC, 2009/355/EC, 2009/365/EC) also authorised the use of lycopene in fats and dressings with a maximum permitted content of 10 mg/100 g.

In its revised exposure assessment from 2010, the ANS Panel noted that most of the maximum use levels as a food colouring were lower than those considered in previous EFSA evaluations (EFSA ANS Panel, 2010).

For scenarios 2–4, the ANS Panel concluded that the revised exposure assessment of lycopene from both the use as a food colouring and natural sources indicated that the potential mean and 95<sup>th</sup> percentile exposures for children were approximately 0.2 mg/kg bw per day and around or slightly below the ADI of 0.5 mg/kg bw per day, respectively (EFSA ANS Panel, 2010). In adults, the 95<sup>th</sup> percentile for lycopene from use as a food colouring and from natural sources was below the ADI. When exposure to lycopene used as a NFI (scenarios 5 and 6) was taken into account, the total exposure was higher in all populations studied. The mean anticipated exposure in children amounted to 0.42–0.5 mg/kg bw per day, and was 44–55 % above the ADI at the 95<sup>th</sup> percentile. The ANS Panel noted that these estimates were based on several conservative assumptions and might overestimate the potential intake, because lycopene was assumed to be present at the maximum permitted level and in all authorised food categories. Moreover, the food categories mentioned in the terms of reference are very broad and can hardly be refined.

Annex III of these Commission Decisions require the holders of the marketing authorisation to collect information for the period from 1 July 2009 to 30 June 2012 on the quantities of lycopene sold to producers of final food products. In addition, authorisation holders should provide an updated intake assessment and, if available, new scientific information for a reconsideration of the maximum safe intake levels of lycopene. According to these Commission Decisions, the Commission shall consult EFSA to review the information provided by industry.



## 2. Additional information provided

The marketing authorisation holders for the use of lycopene as a NFI (BASF, LycoRed, DSM) jointly prepared and submitted a dossier. The dossier contains sales data, product launch data, an intake estimate and toxicological information.

### 2.1. Sales data

The three lycopene manufacturers have supplied the Commission with figures on the amounts of lycopene sold in Europe for three years (1 July 2009 to 30 June 2010, 1 July 2010 to 30 June 2011, 1 July 2011 to 30 June 2012). Two of the manufacturers provided information on the amounts of lycopene sold as a NFI and as a food colouring. For reasons of confidentiality, figures are not presented here. The total amounts of lycopene sold were low. The manufactures indicated that some of these sales may have been used for food products for markets outside of Europe. Sales data provided by the industry indicate an increase of the sales of lycopene as a food colouring but not as a NFI over the period concerned. According to the information provided by the manufacturers, the majority of the reported sales, i.e. 80–90 %, are related to food supplements (Tennant, 2013). Sales for non-supplement novel food applications constitute only around 1–2 % of the reported sales. No figure was given for the use of lycopene as a food colouring for foods other than supplements.

### 2.2. Product launch data

The Mintel Group's Global New Products Database (GNPD)<sup>4</sup> has been searched by the manufacturers for lycopene-containing food products introduced to the market since approvals of lycopene as a NFI were granted. GNPD data from July 2009 to June 2012 were provided to characterise the market for lycopene-containing food products.

For the period from July 2009 to June 2010, the GNPD recorded the launch of 13 new lycopene-containing products. Among these were a meal replacement product and a cereal bar, both with an unspecified content of lycopene, and one flavoured drink with 2.5 mg lycopene per 250 mL. The other products were an oil with a questionable amount of lycopene ("*2.5 % lycopene*") and nine food supplements. The specified daily dose provided for six lycopene-containing supplements ranged between 0.5 mg and 2.5 mg. Information on two supplements indicated a daily dose of 7 and 10 mg per day. Considering the permitted maximum level for lycopene used as a food colouring in food supplements (30 mg/kg), the use of lycopene can be considered as a NFI in these food supplements. The information provided for one food supplement indicates "*20 mg lycopene per 2 tablets daily dose*" which exceeds the dose authorised in the Commission Decisions authorising the NFI lycopene (15 mg per daily dose).

For the period from July 2010 to June 2011, the GNPD recorded the launch of new food products in which lycopene was used as a food colouring (two for each of the food categories non-alcoholic beverages, chewing gum and prepared meals, and one in each category of bakery product, dairy product, chocolate confectionery and meat substitute) and as a food supplement (n = 19). The lycopene content was indicated for 11 of the food supplements (usually providing 1–2 mg lycopene per day; a daily dose of 10 mg was specified for two supplements).

For the period from July 2011 to June 2012, the GNPD recorded the launch of 16 new lycopene-containing food products (13 food supplements; 2 meal replacement products and 1 non-alcoholic beverage). The information provided for one food supplement indicates "*30 mg lycopene per tablet*" which exceeds the dose authorised in the Commission Decisions authorising the NFI lycopene.

In 2013, the three lycopene manufactures asked the Mintel Group to provide an update and information on products which have remained on the market and those which have been withdrawn. According to the GNPD, only 9 out of 26 lycopene products used for food colouring remained on the market, and the sales of nine food supplements have been discontinued. Lycopene-containing food

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<sup>4</sup> <http://www.gnpd.com>

supplements were launched in 10 EU Member States according to data recorded in the GNPD. The information on the daily dose of lycopene ranged, for most food supplements, between 1 and 10 mg. For two food supplements a daily dose of 30 mg lycopene was indicated, which would exceed levels authorised in the Commission Decisions authorising the NFI lycopene and levels permitted as a food colouring.

Only four non-supplement Novel Food products (three meal replacement drinks and a beverage) were identified containing lycopene used as a NFI for 2009–2012. None of these products remained on the market according to the GNPD query for 2013.

The Panel notes that, according to the post launch monitoring data derived from the GNPD and provided by the lycopene manufacturers for the period from July 2009 to June 2012, the only relevant use of lycopene as a NFI concerns its use in food supplements. Lycopene uses other than as a food colouring and as a food supplement ingredient were negligible in the relevant period.

### **2.3. Updated intake estimate by the manufacturers**

The manufacturers jointly conducted an intake estimate (Tennant, 2013). It addresses the same six scenarios as considered by the ANS Panel in 2010 (EFSA ANS Panel, 2010). By taking into account sales and product launch data, the authors concluded that it is very unlikely that the ADI for lycopene is exceeded by any population group. According to this estimate, after natural occurrence, food supplements appear to be the principal source of exposure.

### **2.4. Toxicological information provided by the manufacturers.**

The information (Cockburn and Walker, 2013) provided did not contain new toxicological studies which have not already been considered in the EFSA opinions on lycopene as a NFI and as a food colouring (EFSA, 2008a, b, c, d, 2010). According to the manufacturer's literature review, no new toxicological studies with lycopene became available since then.

## **DISCUSSION**

In 2010, the ANS Panel concluded that the revised exposure assessment of lycopene from both the use as a food colouring and from natural occurrence indicated that the potential mean and 95<sup>th</sup> percentile exposures for children were approximately 0.2 mg/kg bw per day and around, or slightly below, the ADI of 0.5 mg/kg bw per day, respectively. When exposure to lycopene used as a NFI was taken into account, the anticipated mean and the 95<sup>th</sup> percentile exposure in children amounted to 0.42–0.5 mg/kg bw per day and was 44–55 % above the ADI (0.5 mg/kg bw per day), respectively.

According to the post-marketing monitoring programme performed by the manufacturers of lycopene, from mid-2009 to mid-2012, sales of lycopene for both uses, as a food colouring and as a NFI, were low.

The information from the GNPD indicates that lycopene used as a NFI in food supplements is, for the most part, marketed with reported dose levels between 1 and 10 mg lycopene per day, which is below the maximum levels considered by EFSA in its intake estimates in 2008 and those permitted by the Commission Decisions (15 mg). The GNPD also indicated that a few food supplements are marketed with recommended daily doses between 20 and 30 mg, which are above the level authorised by the European Commission of 15 mg per day.

On the basis of information on sales and new product launch data for the period from July 2009 to June 2012 provided by the lycopene manufacturers, food supplements appear to be the main source of lycopene after intake from natural occurrence.

The Panel considers that data provided by the manufacturers indicate that actual intakes of lycopene are below the estimates for lycopene (which are overestimations, because they considered that

lycopene would be added to all permitted food categories at maximum permitted levels (2008a, b, c, d, 2010).

Since no new toxicological studies became available, there is no scientific basis on which the ADI established by EFSA in 2008 could be reconsidered.

## CONCLUSIONS

On the basis of previous intake assessments performed by EFSA and data on sales and product launch data provided for the period from July 2009 to June 2012, the Panel concludes that intakes of naturally occurring lycopene and from its use as a food colouring and as a NFI at permitted use levels do not lead to intakes above the ADI of 0.5 mg/kg bw/day.

## DOCUMENTATION PROVIDED TO EFSA

1. Dossier prepared by the three manufacturers of the Novel Food Ingredient (BASF, LycoRed, DSM).
2. Letter from the European Commission to the European Food Safety Authority with the request for a scientific opinion on “*revision of an exposure assessment on lycopene as a novel food ingredient as a novel food ingredient*” Ref. Ares(2014)1132220 received on 10 April 2014.

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## ABBREVIATIONS

ADI	Acceptable Daily Intake
bw	body weight
GNPD	(Intel Group`s) Global New Products Database
NF(I)	Novel Food (Ingredient)