

ADOPTED: 24 October 2017

AMENDED: 11 December 2017

doi: 10.2903/j.efsa.2017.5064

Extension of use of lycopene (E 160d) to certain meat preparations, meat products and fruit and vegetable preparations

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS),
Maged Younes, Peter Aggett, Fernando Aguilar, Riccardo Crebelli, Birgit Dusemund,
Metka Filipič, Maria Jose Frutos, Pierre Galtier, Ursula Gundert-Remy, Gunter Georg Kuhnle,
Claude Lambré, Jean-Charles Leblanc, Inger Therese Lillegaard, Peter Moldeus,
Alicja Mortensen, Agneta Oskarsson, Ivan Stankovic, Ine Waalkens-Berendsen,
Rudolf Antonius Woutersen, Matthew Wright, Lieve Herman, Paul Tobback, Fabiola Pizzo,
Camilla Smeraldi, Alexandra Tard, Adamantia Papaioannou and David Gott

Abstract

The present scientific opinion deals with the safety of the extension of use of lycopene (E 160d) in certain meat preparations, meat products and fruit and vegetable preparations. Lycopene (E 160d) is an authorised food additive in the EU for use in several food categories and an acceptable daily intake (ADI) of 0.5 mg/kg body weight (bw) per day was established. In the present opinion, the Panel decided that a comparison of the exposure resulting from the current uses and use levels with the exposure resulting from this additional proposed extension of uses would be sufficient to address the safety of lycopene. The Panel calculated that, considering the current maximum permitted levels (MPLs) and the proposed extension of uses and use levels, the mean dietary exposure to lycopene (E 160d) in the total population ranged from 0.01 mg/kg bw per day in infants to 0.82 mg/kg bw per day in toddlers. At the high level, dietary exposure to lycopene (E 160d) ranged from 0.03 mg/kg bw per day in infants to 1.39 mg/kg bw per day in toddlers. The Panel concluded that the proposed extension of uses of lycopene (E 160d) as a food additive in meat preparations, meat products and fruit and vegetable preparations up to 60 mg/kg would not add significantly to the intake of the food additive at its current MPL. However, the Panel noted that the overall intake at the MPL scenario would exceed the currently established ADI. The Panel acknowledged the uncertainties in the current estimates which could result in an overestimation of the exposure to lycopene (E 160d) as a food additive in European countries and therefore concluded that a refined exposure estimate would be recommended focusing on food categories contributing the most to its estimates, in order to decrease uncertainties in its current estimates.

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: food additive, food colour, lycopene, E 160d, extension of use

Requestor: European Commission

Question number: EFSA-Q-2017-00098

Correspondence: fip@efsa.europa.eu

Panel members: Peter Aggett, Fernando Aguilar, Riccardo Crebelli, Alessandro Di Domenico, Birgit Dusemund, Metka Filipič, Maria Jose Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Gunter Georg Kuhnle, Claude Lambré, Jean-Charles Leblanc, Inger Therese Lillegaard, Peter Moldeus, Alicja Mortensen, Agneta Oskarsson, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright and Maged Younes.

Amendment: An editorial correction (edit link to the FAIM 2 tool, page 7) was carried out that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

Suggested citation: EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Younes M, Aggett P, Aguilar F, Crebelli R, Dusemund B, Filipič M, Frutos MJ, Galtier P, Gundert-Remy U, Kuhnle GG, Lambré C, Leblanc J-C, Lillegaard IT, Moldeus P, Mortensen A, Oskarsson A, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Wright M, Herman L, Tobbäck P, Pizzo F, Smeraldi C, Tard A, Papaioannou A and Gott D, 2017. Scientific Opinion on the extension of use of lycopene (E 160d) to certain meat preparations, meat products and fruit and vegetable preparations. *EFSA Journal* 2017;15(12):5064, 24 pp. <https://doi.org/10.2903/j.efsa.2017.5064>

ISSN: 1831-4732

© 2017 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs License](https://creativecommons.org/licenses/by/4.0/), which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



Summary

Following a request from the European Commission, an exposure assessment was carried out based on the maximum permitted levels (MPLs) authorised in Annex II of Regulation (EC) No 1333/2008 for lycopene (E 160d) and the proposed extension of uses in to the categories 08.2 meat preparations as defined by Regulation (EC) No 853/2004, 08.3.1 Non-heat-treated meat products, 08.3.2 Heat-treated-meat products and 04.2.4.1 Fruit and vegetable preparations excluding compote, as proposed by the applicant.

Lycopene (E 160d) is a carotenoid which is currently an authorised food additive (colour) in the European Union (EU) under Annex II Regulation (EC) No 1333/2008 for use in several food categories.

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) has already evaluated the toxicological data on lycopene and derived an acceptable daily intake (ADI) of 0.5 mg/kg bw per day using a safety factor of 100. This ADI refers to lycopene from all sources.

In the present opinion, an anticipated exposure to lycopene (E 160d) as a food additive at the maximum permitted levels (MPLs) was undertaken by the European Food Safety Authority (EFSA), by performing a refined exposure assessment, taking into consideration the current authorised uses and the proposed extension of uses as provided by the applicant. For the exposure assessment scenario, 24 out of the 30 currently authorised food categories were taken into account and 28 food categories if both authorised and proposed food categories are considered.

The Panel noted that the mean dietary exposure to lycopene (E 160d) in the total population, considering the current MPLs and the proposed extension of uses and use levels, ranged from 0.01 mg/kg bw per day in infants to 0.82 mg/kg bw per day in toddlers. At the high level, dietary exposure to lycopene (E 160d) ranged from 0.03 mg/kg bw per day in infants to 1.39 mg/kg bw per day in toddlers. The Panel noted that the ADI of 0.5 mg/kg bw per day is exceeded for toddlers and children at the mean and for toddlers, children and adolescents at the p95. At worst, high level exposure is 2.8 times higher than the ADI (toddlers at the high level).

The Panel concluded that the proposed extension of uses of lycopene (E 160d) as a food additive in meat preparations, meat products and fruit and vegetable preparations up to 60 mg/kg would not add significantly to the intake of the food additive at its current MPL. However, the Panel noted that the overall intake at the MPL scenario would exceed the currently established ADI. The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) acknowledged the uncertainties in the current estimates which could result in an overestimation of the exposure to lycopene (E 160d) as a food additive in European countries and therefore concluded that a refined exposure estimate would be recommended in order to decrease uncertainties in its current estimates.

The Panel concluded also that exposure estimates calculated for the current assessment are not directly comparable with the previous opinion (EFSA, 2010) owing to the changes in the underlying consumption data and use levels used for the exposure assessment and different methodology applied.

Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	5
1.1. Background and Terms of Reference as provided by the European Commission	5
1.1.1. Background	5
1.1.2. Terms of Reference	6
1.2. Information on existing authorisation and evaluations.....	6
2. Data and methodologies.....	6
2.1. Data.....	6
2.2. Methodologies.....	7
3. Assessment.....	7
3.1. Technical data.....	7
3.2. Authorised and the proposed extension of uses and use levels	7
3.3. Food consumption data used for exposure assessment	9
3.3.1. EFSA Comprehensive European Food Consumption Database	9
3.3.2. Food categories considered for the exposure assessment of lycopene (E 160d)	10
3.4. Summarised data extracted from the Mintel's Global New Products Database	11
3.5. Exposure estimates	12
3.5.1. Exposure to lycopene (E 160d) from its current uses and the proposed extension of uses as a food additive	12
3.5.1.1. Dietary exposure to lycopene (E 160d)	13
3.5.2. Main food categories contributing to exposure to lycopene (E 160d) using the current MPLs and the current MPLs and the proposed extension of use levels.....	13
3.5.3. Exposure via the regular diet.....	14
3.6. Uncertainty analysis.....	14
3.7. Discussion	15
4. Conclusions.....	15
5. Recommendations.....	15
Documentation provided to EFSA	16
References.....	16
Abbreviations.....	16
Appendix A – Summary of total estimated exposure of lycopene (E 160d) from its use as a food additive using the current MPLs and the current MPLs + the proposed extension of use levels per population group and survey: mean and high level (mg/kg bw per day).....	17
Appendix B – Main food categories contributing to exposure to lycopene (E 160d) using the current MPLs and the current MPLs + the proposed extension of use levels	20
Appendix C – Number and percentage of food products labelled with lycopene (E 160d) out of the total number of food products present in the Mintel GNPD per food sub-category between 2012 and 2017 ^(a)	24

1. Introduction

The present scientific opinion deals with the safety of the extension of use of lycopene (E 160d) in meat preparations, non-heat-treated meat products, heat-treated-meat products and fruit and vegetable preparations excluding compote.

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008 on food additives¹. Only food additives that are included in the Union list, in particular in Annex II to that Regulation, may be placed on the market and used in foods under the conditions of use specified therein.

Lycopene (E 160d) is a carotenoid which is currently an authorised food additive (colour) in the European Union under Annex II Regulation (EC) No 1333/2008 for use in several food categories.

The Health and Food Safety Directorate-General received an application from LycoRed Ltd. in June 2012 as regards the extension of use of lycopene (E 160d) in meat preparations and meat products. At that time it was not possible to progress with the application since the EFSA opinion² indicated that potential intakes of lycopene from use as a food colour, from natural occurrence and from fortified foods might exceed the ADI, particularly for children.

The authorisations of lycopene as a novel food ingredient established a monitoring programme on its use. In January 2015, based on the data collected, EFSA issued a statement on the post-marketing monitoring of the use of lycopene³ in which it was concluded that intakes of naturally occurring lycopene and from its use as a food colour and as a novel food ingredient at permitted use levels do not lead to intakes above the ADI (EFSA NDA Panel, 2015).

Following the EFSA's statement, the applicant resubmitted its request in August 2015. The application was discussed with the Member States at the meeting of the Working Party of Governmental Experts on Additives in January 2016 where it was found appropriate to consult EFSA as regards the safety of proposed extension of use. In addition, it was pointed out that the proposed extension do not accurately reflect the applicable restrictions/exceptions for other red/yellow colours authorised for use in the relevant food categories. The applicant was informed accordingly. On that basis, the applicant submitted an amendment to its application in December 2016 requesting the following:

- The use of lycopene (E 160d) in food category 08.2 "Meat preparations as defined by Regulation (EC) No 853/2004" at the maximum level of 50 mg/kg with the following restriction: only breakfast sausages with a minimum cereal content of 6%, burger meat with a minimum vegetable and/or cereal content of 4% mixed within the meat (in these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance), merguez type products, salsica fresca, butifarra fresca, longaniza fresca, chorizo fresco, cevapcici and pljeskavice
- The use of lycopene (E 160d) in food category 08.3.1 "Non-heat-treated meat products" at the maximum level of 50 mg/kg with the following restriction: only chorizo sausage/salchichon, sausages and pasturmas
- The use of lycopene (E 160d) in food category 08.3.2 "Heat-treated-meat products" at the maximum level of 50 mg/kg with the following restriction: only sausages, patés and terrines
- The use of lycopene (E 160d) in food category 04.2.4.1 "Fruit and vegetable preparations excluding compote" at the maximum level of 60 mg/kg with the following restriction: only preserves of red fruit, mostarda di frutta and seaweed based fish roe analogues

¹ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

² EFSA Journal 2010; 8(1):1444, 26 pp.

³ EFSA Journal 2015; 13(1):3955, 11 pp.

1.1.2. Terms of Reference

The European Commission requests the European Food Safety Authority to provide a scientific opinion on the safety of the proposed extension of use of lycopene (E 160d) to the categories 08.2 Meat preparations as defined by Regulation (EC) No 853/2004⁴, 08.3.1 Non-heat-treated meat products, 08.3.2 Heat-treated-meat products and 04.2.4.1 Fruit and vegetable preparations excluding compote in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.⁵

1.2. Information on existing authorisation and evaluations

Lycopene (E 160d) (lycopene from red tomatoes, lycopene from *Blakeslea trispora* and synthetic lycopene) is authorised as a food colour within the EU in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012⁶.

Lycopene (E 160d) was previously assessed in 2008 for its use as a food additive by the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC), also taking into account previous evaluations and authorisations, who evaluated the toxicological data on lycopene and derived an acceptable daily intake (ADI) of 0.5 mg/kg body weight (bw) per day using a safety factor of 100. This ADI refers to lycopene from all sources (EFSA AFC Panel, 2008).

In addition, the same year, 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 (LycoRed) and cold water-dispersible lycopene products from *Blakeslea trispora* (DSM) (EFSA NDA Panel, 2008a,b,c). In its three opinions on lycopene as a novel food ingredient (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 per day.

In 2010, EFSA undertook a revised exposure assessment for lycopene as a food colour (EFSA, 2010). In this assessment, in which not only natural source but also combined use of lycopene as a novel food and as a food colour were taken into account, the overall conclusion was that the use of lycopene would be expected to remain within the ADI, even for high consumer children. Only in case of an additional intake of lycopene from fortified foods, the intake of lycopene might possibly exceed the ADI. EFSA noted, however, that these estimates were based on several conservative assumptions and might overestimate the potential intake.

In 2015, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) has issued a statement on the post-marketing monitoring of the use of lycopene. The NDA Panel 'concluded that data on sales and product launch data provided for the period from July 2009 to June 2012 by the manufacturers indicated 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 per day' (EFSA NDA Panel, 2015).

2. Data and methodologies

2.1. Data

The Panel noted that the applicant submitted a dossier in support of its application for the extension of the approved uses (additional food categories) of lycopene (E 160d) in the EU ('Documentation provided to EFSA' No. 1).

The Panel noted that the applicant provided the results of a UK study on intakes of lycopene (E 160d) in children (Tennant, 2010 - 'Documentation provided to EFSA' No. 1). According to the study, 'the effect of adding use of lycopene in sausage, pates and similar products is to cause a marginal increase in intakes of lycopene from all sources'. In addition, it is stated that the primary source of lycopene for high level consumers are tomato-based sauces, which indicates that the

⁴ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. OJ L 226, 26.5.2004, p. 1–22.

⁵ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 354, 31.12.2008, p. 1–6.

⁶ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1.

extension of use of lycopene to other food categories would not significantly affect the high level intakes.

The Panel concluded that the study provided by the applicant is not adequate to assess the safety of the proposed extension of uses of lycopene in the context of the EU consumers. This is due to the fact that the applicant considered in its evaluation only one EU Member State (UK) rather than considering all the EU Members States by the use of the Food Additives Intake Model (FAIM) template as recommended by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) in its guidance for submission for food additives evaluations (EFSA ANS Panel, 2012).

2.2. Methodologies

The current 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012) has been followed by the EFSA ANS Panel for the evaluation of the proposed extension of the authorisation of the already authorised food additive lycopene (E 160d) in the new food categories.

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

Dietary exposure to lycopene (E 160d) from its proposed extension of use as a food additive was estimated by the Panel combining the food consumption data available within the EFSA Comprehensive European Food Consumption Database with the proposed extension of use levels provided by the applicant, using EFSA's FAIM tool (version 2) <http://www.efsa.europa.eu/en/applications/foodingredients/tools>. However, the Panel decided not to use the estimate of exposure generated from the FAIM tool because the aggregation of the data resulted in an overestimation of the exposure. The Panel therefore decided to perform a more refined assessment, limited to the food categories mentioned in Section 3.5.2.

3. Assessment

3.1. Technical data

The Panel noted that the applicant did not submit any evidence on specifications for lycopene (E 160d).

According to the applicant, the specifications for lycopene are the same as those set out in Annex II and III to Regulation (EC) No 1333/2008, for the entry E 160d.

3.2. Authorised and the proposed extension of uses and use levels

Maximum levels of lycopene (E 160d) have been defined in Annex II to Regulation (EC) No 1333/2008 on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

The Panel note that lycopene (E 160d) is currently an authorised food additive in the EU with MPLs ranging from 5 to 500 mg/kg in 30 food categories, as listed in Table 1.

Table 1 summarises foods that are currently authorised to contain lycopene (E 160d) and the corresponding MPLs and foods that are proposed to be authorised for containing lycopene (E 160d) (n = 4 food categories) and the corresponding proposed maximum levels.

Table 1: Current uses and MPLs of lycopene (E 160d) in foods according to the Annex II of Regulation (EC) No 1333/2008 as amended and the proposed extension of uses and maximum levels

Food category number	Food category name	Restrictions/exceptions	Maximum permitted level (mg/L or mg/kg as appropriate)	Proposed extension of uses (mg/L or mg/kg as appropriate)
01.4	Flavoured fermented milk products including heat-treated products		30	
01.7.3	Edible cheese rind		30	
01.7.5	Processed cheese	Only flavoured processed cheese	5	

Food category number	Food category name	Restrictions/exceptions	Maximum permitted level (mg/L or mg/kg as appropriate)	Proposed extension of uses (mg/L or mg/kg as appropriate)
03	Edible ices		40	
04.2.4.1	Fruit and vegetable preparations excluding compote	Only preserves of red fruit, <i>mostarda di frutta</i> , and seaweed based fish roe analogues		60
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC	Except chestnut purée	10 ^(a)	
04.2.5.3	Other similar fruit or vegetable spreads	Except <i>crème de pruneaux</i>	10 ^(a)	
05.2	Other confectionery including breath freshening microsweets		30	
05.3	Chewing gum		300	
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Except red coating of hard-sugar coated chocolate confectionery	30	
		Only red coating of hard-sugar coated chocolate confectionery	200	
06.6	Batters	Only batters for coating	30	
07.2	Fine bakery wares		25	
08.2	Meat preparations	Only <i>breakfast sausages</i> with a minimum cereal content of 6%, <i>burger meat</i> with a minimum vegetable and/or cereal content of 4% mixed within the meat ^(b) , merguez type products, <i>salsicha fresca</i> , <i>mici</i> , <i>butifarra fresca</i> , <i>longaniza fresca</i> , <i>chorizo fresco</i> , <i>cevapcici</i> and <i>pljeskavice</i>		50
08.3.1	Non-heat-treated meat products	Only chorizo sausage/salchichon, sausages and pasturmas		50
08.3.2	Heat-treated meat products	Only sausages, patés and terrines		50
08.3.3	Casings and coating and decorations for meat	Only decorations and coatings except edible external coating of <i>pasturmas</i>	500	
		Only edible casings	30	
09.2	Processed fish and fishery products including molluscs and crustaceans	Only salmon substitute	10	
		Only fish and crustacean paste, precooked crustaceans, surimi, smoked fish	30	
09.3	Fish roe	Except Sturgeons' eggs (Caviar)	30	
12.2.2	Seasonings and condiments		50	
12.5	Soups and broths		20	
12.6	Sauces	Excluding tomato-based sauces	50	
12.9	Protein products, excluding products covered in category 1.8	Only meat and fish analogues based on vegetable proteins	30	

Food category number	Food category name	Restrictions/exceptions	Maximum permitted level (mg/L or mg/kg as appropriate)	Proposed extension of uses (mg/L or mg/kg as appropriate)
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		30	
13.3	Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)		30	
14.1.4	Flavoured drinks	Excluding dilutable drinks	12	
14.2.4	Fruit wine and made wine	Excluding <i>wino owocowe markowe</i>	10	
14.2.7.3	Aromatised wine-product cocktails		10	
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol		30	
15.1	Potato-, cereal-, flour- or starch-based snacks		30	
15.2	Processed nuts		30	
16	Desserts excluding products covered in categories 1, 3 and 4		30	
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms		30	
17.2	Food supplements supplied in a liquid form		30	
17.3	Food supplements supplied in a syrup-type or chewable form		30	

(a): Maximum individually or in combination with E 120, E 142, E 160d and E 161b.

(b): In these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with the fat, giving those products their typical appearance.

Lycopene (E 160d) is not authorised to be added in foods according to Annex III to Regulation (EC) No 1333/2008.

3.3. Food consumption data used for exposure assessment

3.3.1. EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure

Assessment' (EFSA, 2011a). New consumption surveys added in the Comprehensive database were also taken into account in this assessment.⁷

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database represents the best available source of food consumption data across Europe at present.

Food consumption data from the following population groups: infants, toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 2).

Table 2: Population groups considered for the exposure estimates of lycopene (E 160d)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK
Children ^(a)	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Spain, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly ^(a)	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Sweden, UK

(a): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, the FoodEx food codes were matched to the FCS food categories.

3.3.2. Food categories considered for the exposure assessment of lycopene (E 160d)

The food categories in which the use of lycopene (E 160d) is authorised and the proposed extension of uses were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

Some food categories or their restrictions/exceptions are not referenced in the EFSA Comprehensive Database and could therefore not be taken into account in the present estimate. This was the case for 6 food categories and may have resulted in an underestimation of the exposure. The food categories which were not taken into account are (in ascending order of the FCS codes):

- 01.7.3 Edible cheese rind,
- 06.6 Batters,
- 08.2 Meat preparations as defined by Regulation (EC) No 853/2004, only *breakfast sausages* with a minimum cereal content of 6%, *burger meat* with a minimum vegetable and/or cereal content of 4% mixed within the meat (in these products, the meat is minced in such a way so that the muscle and fat tissue are completely dispersed, so that fibre makes an emulsion with

⁷ Available online: <http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm>

the fat, giving those products their typical appearance), merguez type products, *salsicha fresca*, *mici*, *butifarra fresca*, *longaniza fresca*, *chorizo fresco*, *cevapcici* and *pljeskavice*

- 08.3.3 Casings and coatings and decorations for meat.
- Concerning the food categories 13.2 and 13.3, these are foods for special medical purposes (FSMP) for populations which are not infants and young children. FSMP consumed in children, adolescents, adults and the elderly may be very diverse; they cannot be considered because of very limited information on consumption. Eating occasions belonging to the food categories 13.2, 13.3 were therefore reclassified under food categories in accordance to their main component and are not taken into account in the current assessment.

Therefore, for the exposure assessment scenario, 24 out of the 30 currently authorised food categories were taken into account and 28 food categories if both authorised and the proposed extension of food categories are considered.

For the following food categories, the restrictions/exceptions which apply to the use of lycopene (E 160d) could not or not totally be taken into account.

For the food category 01.7.5 Processed cheese, the restriction/exception 'only flavoured processed cheese' could not be taken into account; therefore, the whole food category was taken into account. This may have resulted in an overestimation of the exposure.

For the food category 04.2.4.1 fruit and vegetable preparations excluding compote, the restrictions/exceptions '*mostarda di frutta*, and seaweed based fish roe analogues' could not be taken into account, and therefore, only the preserves of red fruit (i.e. canned red fruits) were considered in the exposure assessment. This may have resulted in an underestimation of the exposure.

For the food category 05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4, the restriction/exception 'only red coating of hard-sugar coated chocolate confectionery' could not be taken into account; therefore, the whole food category was considered at the MPL of 30 mg/kg. This may have resulted in an underestimation of the exposure.

For the food category 09.2 Processed fish and fishery products including molluscs and crustaceans, the restrictions/exceptions 'only smoked fish' which apply to the use of lycopene (E 160d) could not be taken into account, and therefore, fishes which are usually smoked were taken into account i.e. herring, salmon, trout, anchovy, mackerel, sardine and pilchard. This may have resulted in an overestimation of the exposure.

For the food category 09.3 Fish roe, the restrictions/exceptions 'except Sturgeons' eggs (Caviar)' could not be taken into account; therefore, the whole food category was taken into account. This may have resulted in an overestimation of the exposure.

For the food category 12.9 Protein products, excluding products covered in category 1.8, the restrictions/exceptions 'only meat and fish analogues based on vegetable proteins' could not be taken into account; therefore, the whole food category was taken into account. This may have resulted in an overestimation of the exposure.

For the food category 14.1.4 Flavoured drinks, the restrictions/exceptions 'excluding dilutable drinks' could not be taken into account; therefore, the whole food category was taken into account. This may have resulted in an overestimation of the exposure.

For the food category 14.2.4 Fruit wine and made wine, the restrictions/exceptions 'excluding *wino owocowe markowe*' could not be taken into account therefore, the whole food category was taken into account. This may have resulted in an overestimation of the exposure.

All other refinements considering the restrictions/exceptions detailed in Table 1 were fully applied.

It has to be noted that in each food categories, all foods were selected and not only those which may be red coloured, except when specified in restrictions. This should result in an overestimation of the exposure.

3.4. Summarised data extracted from the Mintel's Global New Products Database

The Mintel's GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 2 million food and beverage products of which more than 900,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently having 20 out of its 28 member countries and Norway presented in the Mintel GNPD.⁸

⁸ Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.

For the purpose of this Scientific Opinion, the Mintel's GNPD⁹ was used for checking the labelling of food and beverage products and food supplements for lycopene (E 160d) within the EU's food market as the database contains the compulsory ingredient information on the label.

According to the Mintel's GNPD, lycopene (E 160d) was labelled on approximately 250 products since 2000, of which 186 were found to be published in this database between 2012 and 2017. Lycopene (E 160d) was found to be labelled only on 10 categories. The main ones on which lycopene was labelled were meal replacements, food supplements and meat substitutes. At the maximum, the percentage of foods labelled to contain lycopene (E 160d) was 3.2% in the Mintel's GNPD food subcategory 'Meal Replacements & Other Drinks'; the average percentage was 0.5%.

EFSA does not collect information on the specific brand products consumed and thus the proportion of products containing lycopene (E 160d) could not be accounted for the exposure assessment. In the current exposure estimates, all foods belonging to food categories authorised according to the legislation were taken into account.

Appendix C lists the percentage of the food products labelled with lycopene (E 160d) between 2012 and 2017, out of the total number of food products per food subcategory according to the Mintel's GNPD food classification.

According to the Mintel's GNPD, lycopene (E 160d) was not labelled in the following food subcategories, while these are authorised to contain E 160d according to Annex II to Regulation No 1333/2008:

- 1.7 Cheeses products
- 3 Edible ices
- 5.2 Other confectionery including breath freshening micro-sweets
- 5.3 Chewing gum
- 5.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4
- 6.6 Batters
- 7.2 Fine bakery wares
- 8.3.3 Casings and coating and decorations for meat
- 9.2 Processed fish and fishery products including molluscs and crustaceans
- 9.3 Fish roe
- 12.2.2 Seasonings and condiments
- 12.5 Soups and broths
- 12.6 Sauces
- 12.9 Protein products, excluding products covered in category 1.8
- 14.2.4 Fruit wine and made wine
- 14.2.7.3 Aromatised wine-product cocktails
- 14.2.8 Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol

Thus, taking these food categories into account in the exposure estimates may have resulted in an overestimation of the exposure.

3.5. Exposure estimates

3.5.1. Exposure to lycopene (E 160d) from its current uses and the proposed extension of uses as a food additive

The Panel estimated chronic exposure to lycopene (E 160d) for the following population groups: infants; toddlers, children, adolescents, adults and the elderly. Dietary exposure to lycopene (E 160d) was calculated by multiplying lycopene (E 160d) concentrations for each food category (Table 1) with their respective consumption amount per kilogram of body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

⁹ <http://www.gnpd.com/sinatra/home/> accessed on 18/9/2017.

This was carried out for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 2). On the basis of these distributions, the mean and 95th percentile of exposure was calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups where the sample size was sufficiently large to allow this calculation (EFSA, 2011a). Therefore, in the present assessment, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain were not included.

Exposure assessment to lycopene (E 160d) was carried out by the ANS Panel based on two different sets of concentration data: (1) current MPLs as set down in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*); and (2) current MPLs as set down in the EU legislation and the proposed extension of use levels.

These scenarios consider the consumption of food supplements.

3.5.1.1. Dietary exposure to lycopene (E 160d)

Table 3 summarises the estimated exposure to lycopene (E 160d) from its use as a food additive in six population groups (Table 2) according to the different exposure scenarios. Detailed results per population group and survey are presented in Appendix A.

Table 3: Summary of dietary exposure to lycopene (E 160d) from their use as a food additive at the current MPLs and at the current MPLs and the proposed extension of use levels, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks– 11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Exposure assessment scenario: Current MPLs						
Mean	0.01–0.13	0.17–0.78	0.15–0.60	0.07–0.33	0.04–0.17	0.02–0.12
95th percentile	0.03–0.43	0.46–1.29	0.34–1.21	0.18–0.66	0.10–0.38	0.06–0.26
Exposure assessment scenario: Current MPLs + proposed use levels						
Mean	0.01–0.14	0.18–0.82	0.17–0.63	0.08–0.35	0.05–0.18	0.04–0.13
95th percentile	0.03–0.50	0.52–1.39	0.38–1.25	0.20–0.67	0.14–0.39	0.10–0.27

MPL: maximum permitted level; bw: body weight.

3.5.2. Main food categories contributing to exposure to lycopene (E 160d) using the current MPLs and the current MPLs and the proposed extension of use levels

In the *current MPLs exposure assessment scenario*, the main contributing food categories to the total mean exposure estimates for infants were flavoured fermented milk products including heat-treated products, fine bakery wares, soups and broths, and processed fruits and vegetables. For toddlers, children and adolescents, the main contributing food categories were flavoured fermented milk products and fine bakery wares together with flavoured drinks for children and adolescents; for adults and the elderly, the main contributing food categories were fine bakery wares and flavoured drinks.

In the scenario including both current and the proposed extension of use levels, the main contributing food categories for infants were flavoured fermented milk products including heat-treated products, fine bakery wares, and soups and broths. For toddlers, the main contributing food categories were flavoured fermented milk products and fine bakery wares together with flavoured drinks for children. For adolescents, they were fine bakery wares and flavoured drinks; for adults, meat products and flavoured drinks; and for the elderly, fine bakery wares and meat products.

The main food categories contributing to the exposure to lycopene (E 160d) are presented in Appendix B.

Appendix B can be found in the online version of this output ('Supporting information' section): <https://doi.org/10.2903/j.efsa.2017.5064>

3.5.3. Exposure via the regular diet

In 2010, EFSA estimated the intake of lycopene from natural sources. For children, only data were available from France (3–10 years old) and UK (1.5–4.5 years old). The estimates were 0.13 and 0.14 mg/kg bw per day at the mean and 0.32 and 0.44 mg/kg bw per day at the high level, respectively. Data for adult were available only from UK. The mean estimate was 0.08 mg/kg bw per day and the high level, 0.3 mg/kg bw per day. Comparing with current exposure estimates from food additive for the same countries, intake from food additive would represent between 40% and 65% of total intake (food additive + natural diet) respectively for adults and children.

3.6. Uncertainty analysis

Uncertainties in the exposure assessment of lycopene (E 160d) have been discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 4.

Table 4: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction ^(a)
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/-
Use of data from food consumption surveys covering only a few days to estimate high percentiles (95th) long-term (chronic) exposure	+
Food categories selected for the exposure assessment: exclusion of food categories due to missing FoodEx linkage (n = 6/30 food categories)	-
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception (n = 8/30 food categories)	+
Regulatory maximum level exposure assessment scenario: <ul style="list-style-type: none"> • exposure calculations based on the MPL according to Annex II to Regulation (EC) No 1333/2008 (all authorised food categories taken into account) • All foods within food categories taken into account contain the food additive 	+
Exposure assessment scenario: current MPLs and the proposed extension of use levels <ul style="list-style-type: none"> • exposure calculations based on the MPL according to Annex II to Regulation (EC) No 1333/2008 (all authorised food categories taken into account) • exposure calculations based on proposed maximum levels • All foods within food categories taken into account contain the food additive 	+

(a): +, uncertainty with potential to cause overestimation of exposure; -, uncertainty with potential to cause underestimation of exposure.

In the present assessment, 24 out of the 30 food categories in which lycopene is already authorised were taken into account. The Panel noted that the main food categories in terms of consumption are included in the assessment (fine bakery wares, flavoured drinks, flavoured fermented milk products, soups). The Panel also noted that levels used in the assessment are only maximum levels (permitted or proposed extension) and it is unlikely that all food within the food category will contain the food additive at the maximum level.

Indeed, according to the Mintel GNPD (Appendix C), 10 Mintel categories in which lycopene is already authorised are labelled with the food additive. On average, 0.5% of the foods in each category are labelled with lycopene (E 160d) whereas in the calculation, all food categories from Table 1 and all foods in these categories were taken into account in the estimates. The Panel noted that any fines bakery wares are labelled with the food additive which would result in an overestimation of estimates if these findings were confirmed. The Panel also noted that the restrictions/exceptions 'excluding dilutable drinks' could not be taken into account which may have resulted in an overestimation in the exposure assessment.

Overall, the Panel considered that the uncertainties identified would, in general, result in an overestimation of the exposure to lycopene (E 160d) as a food additive in European countries considered in the EFSA European database for the regulatory maximum level exposure scenario and the exposure assessment scenario considering current MPLs and the proposed extension of use levels.

3.7. Discussion

The European Commission asked EFSA to provide a scientific opinion on the safety of the proposed extension of use of lycopene (E 160d) as a food additive in several food categories, in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

In order to address the safety of this proposed extension of use, the ANS Panel has decided that a comparison of the exposure resulting from the current uses and use levels with the exposure resulting from this additional proposed extension of uses would be sufficient to address the safety of lycopene.

In the present opinion, an anticipated exposure with MPLs to lycopene (E 160d) as a food additive has been undertaken by EFSA taking into consideration the current authorised uses and the proposed extension of uses as provided by the applicant.

Considering the current MPLs, the mean dietary exposure to lycopene (E 160d) in the total population ranged from 0.01 mg/kg bw per day in infants to 0.78 mg/kg bw per day in toddlers. At the high level, dietary exposure to lycopene (E 160d) ranged from 0.03 mg/kg bw per day in infants to 1.29 mg/kg bw per day in toddlers. With the current authorised uses, the ADI of 0.5 mg/kg bw per day is exceeded for toddlers and children at the mean and for toddlers, children and adolescents at the p95. At worst, high level exposure is 2.6 times higher than the ADI (toddlers at the high level).

Considering the current MPLs and the proposed extension of uses and use levels, the mean dietary exposure to lycopene (E 160d) in the total population ranged from 0.01 mg/kg bw per day in infants to 0.82 mg/kg bw per day in toddlers. At the high level, dietary exposure to lycopene (E 160d) ranged from 0.03 mg/kg bw per day in infants to 1.39 mg/kg bw per day in toddlers.

The Panel noted that the proposed extension of uses would not add significantly to the exposure of the food additive in comparison to the exposure considering the current authorised MPLs. In both scenarios, the main food categories contributing to exposure to lycopene (E 160d) were flavoured fermented milk products, fine bakery wares, soups and broths, and flavoured drinks.

For countries in which the ADI is exceeded at the mean for children (Belgium, the Netherlands, Appendix A), exposure estimates are similar to estimates in 2010 opinion.

The ANS Panel is aware that the NDA Panel statement (EFSA NDA Panel, 2015) reached different conclusion given the different framework and data on which the evaluations of both Panels were based. The NDA statement based its conclusion on a document provided by an applicant on sales data, products launch data, revised conclusion on EFSA (2010) intake estimates based on the previously mentioned data and toxicological information. The ANS Panel is following the recently published approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation (EFSA ANS Panel, 2017), which is described in ANS Panel opinions since 2014. Thus, intake estimates in this opinion are based on data from the most comprehensive food consumption database available across Europe and MPLs (in comparison to typical use levels used in 2010) and the proposed extension of use levels.

4. Conclusions

The Panel concluded that the proposed extension of use of lycopene (E 160d) as a food additive in meat preparations, meat products and fruit and vegetable preparations up to 60 mg/kg would not add significantly to the intake of the food additive at its current MPL. However, the Panel noted that the overall intake at the MPL scenario would exceed the currently established ADI. The ANS Panel acknowledged the uncertainties in the current estimates which could result in an overestimation of the exposure to lycopene (E 160d) as a food additive in European countries (see Section 3.6) and therefore concluded that a refined exposure estimate would be recommended in order to decrease uncertainties in its current estimates.

5. Recommendations

The Panel recommended that data on actual use and use levels could be made available to inform a refined exposure assessment according to the Panel current exposure approach. These data should especially focus on food categories contributing the most to these estimates (fermented milk products, fine bakery wares, soups and broths, and flavoured drinks). It should also be requested to give information on the non-use of the food additive in food categories (see Section 3.4) or part of food categories (e.g. in flavoured drinks other than flavoured milk as only flavoured milk were reported to be labelled with lycopene according to Mintel).

Documentation provided to EFSA

- 1) Application for the modification of the conditions on use of lycopene. August 2015 (updated December 2016). Submitted by LycoRed Ltd.

References

- EFSA (European Food Safety Authority), 2007. Guidance of the Scientific Committee on a request from EFSA related to Uncertainties in Dietary Exposure Assessment. *EFSA Journal* 2006;5(1):438, 54 pp. <https://doi.org/10.2903/j.efsa.2007.438>
- EFSA (European Food Safety Authority), 2010. Revised exposure assessment for lycopene as a food colour on request from the European Commission. *EFSA Journal* 2010;8(1):1444, 26 pp. <https://doi.org/10.2903/j.efsa.2010.1444>
- EFSA (European Food Safety Authority), 2011a. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. *EFSA Journal* 2011;9(3):2097, 34 pp. <https://doi.org/10.2903/j.efsa.2011.2097>
- EFSA (European Food Safety Authority), 2011b. Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. *EFSA Journal* 2011;9(3):1970, 27 pp. <https://doi.org/10.2903/j.efsa.2011.1970>
- EFSA AFC Panel (EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food), 2008. Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission on the safety in use of lycopene as a food colour. *EFSA Journal* 2008; 674, 66 pp. <https://doi.org/10.2903/j.efsa.2008.674>
- EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2012. Guidance for submission for food additive evaluations. *EFSA Journal* 2012;10(7):2760, 60 pp. <https://doi.org/10.2903/j.efsa.2012.2760>
- EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2017. Approach followed for the refined exposure assessment as part of the safety assessment of food additives under re-evaluation. *EFSA Journal* 2017;15(10):5042, 9 pp. <https://doi.org/10.2903/j.efsa.2017.5042>
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2008a. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on the safety of synthetic lycopene. *EFSA Journal* 2008;676, 25 pp. <https://doi.org/10.2903/j.efsa.2008.676>
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2008b. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on the safety of lycopene oleoresin from tomatoes. *EFSA Journal* 2008; 675, 22 pp. <https://doi.org/10.2903/j.efsa.2008.675>
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2008c. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on the safety of 'lycopene cold water dispersible products from *Blakeslea trispora*'. *EFSA Journal* 2008;893, 15 pp. <https://doi.org/10.2903/j.efsa.2008.893>
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Statement on the post-marketing monitoring of the use of lycopene. *EFSA Journal* 2015;13(1):3955, 11 pp. <https://doi.org/10.2903/j.efsa.2015.3955>
- EFSA Scientific Committee, 2009. Guidance on transparency in the scientific aspects of risk assessment carried out by EFSA. Part 2: general principles. *EFSA Journal* 2009;7(5):1051, 22 pp. <https://doi.org/10.2903/j.efsa.2009.1051>

Abbreviations

ADI	acceptable daily intake
AFC Panel	Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
ANS Panel	EFSA Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
FAIM	Food Additives Intake Model
FCS	Food Categorisation System
FSMP	foods for special medical purposes
MPL	maximum permitted level
NDA Panel	EFSA Panel on Dietetic Products, Nutrition and Allergies
NFI	novel food ingredient
WHO	World Health Organization

Appendix A – Summary of total estimated exposure of lycopene (E 160d) from its use as a food additive using the current MPLs and the current MPLs + the proposed extension of use levels per population group and survey: mean and high level (mg/kg bw per day)

Population groups	Country	Survey	Number of subjects	Current MPLs		Current MPLs + proposed extension of uses	
				Mean	P95	Mean	P95
Infants	Bulgaria	NUTRICHILD	659	0.05	0.23	0.06	0.26
Infants	Denmark	IAT 2006_07	826	0.10	0.41	0.14	0.50
Infants	Finland	DIPP_2001_2009	500	0.01	0.03	0.01	0.03
Infants	Germany	VELS	159	0.11	0.43	0.13	0.49
Infants	Italy	INRAN_SCAI_2005_06	12	0.06		0.06	
Infants	United Kingdom	DNSIYC_2011	1,369	0.13	0.43	0.14	0.44
Toddlers	Belgium	Regional_Flanders	36	0.78		0.82	
Toddlers	Bulgaria	NUTRICHILD	428	0.18	0.46	0.21	0.52
Toddlers	Denmark	IAT 2006_07	917	0.21	0.54	0.31	0.68
Toddlers	Finland	DIPP_2001_2009	500	0.17	0.60	0.18	0.62
Toddlers	Germany	VELS	348	0.40	0.85	0.48	0.96
Toddlers	Italy	INRAN_SCAI_2005_06	36	0.18		0.19	
Toddlers	Netherlands	VCP_kids	322	0.59	1.29	0.65	1.39
Toddlers	Spain	enKid	17	0.26		0.31	
Toddlers	United Kingdom	DNSIYC_2011	1,314	0.26	0.62	0.29	0.67
Toddlers	United Kingdom	NDNS-RollingProgramme Years1-3	185	0.33	0.63	0.37	0.72
Children	Austria	ASNS_Children	128	0.23	0.51	0.28	0.55
Children	Belgium	Regional_Flanders	625	0.60	1.21	0.63	1.25
Children	Bulgaria	NUTRICHILD	433	0.21	0.51	0.26	0.63
Children	Czech Republic	SISP04	389	0.27	0.61	0.31	0.66
Children	Denmark	DANSDA 2005-08	298	0.21	0.45	0.27	0.57
Children	Finland	DIPP_2001_2009	750	0.22	0.53	0.28	0.59
Children	France	INCA2	482	0.27	0.53	0.31	0.60
Children	Germany	EsKiMo	835	0.20	0.45	0.27	0.55
Children	Germany	VELS	293	0.41	0.77	0.48	0.87
Children	Greece	Regional_Crete	838	0.20	0.44	0.20	0.45
Children	Italy	INRAN_SCAI_2005_06	193	0.15	0.34	0.17	0.38
Children	Latvia	EFSA_TEST	187	0.25	0.53	0.30	0.60
Children	Netherlands	VCPBasis_AVL2007_2010	447	0.51	0.91	0.55	0.99
Children	Netherlands	VCP_kids	957	0.54	1.15	0.59	1.21
Children	Spain	NUT_INK05	399	0.31	0.67	0.36	0.71
Children	Spain	enKid	156	0.26	0.64	0.31	0.68
Children	Sweden	NFA	1,473	0.44	0.85	0.50	0.92
Children	United Kingdom	NDNS-RollingProgramme Years1-3	651	0.31	0.57	0.34	0.62
Adolescents	Austria	ASNS_Children	237	0.14	0.33	0.17	0.38
Adolescents	Belgium	Diet_National_2004	576	0.22	0.44	0.24	0.46
Adolescents	Cyprus	Childhealth	303	0.07	0.18	0.08	0.20

Population groups	Country	Survey	Number of subjects	Current MPLs		Current MPLs + proposed extension of uses	
				Mean	P95	Mean	P95
Adolescents	Czech Republic	SISP04	298	0.19	0.45	0.23	0.50
Adolescents	Denmark	DANSDA 2005-08	377	0.13	0.28	0.15	0.31
Adolescents	Finland	NWSSP07_08	306	0.10	0.24	0.12	0.26
Adolescents	France	INCA2	973	0.14	0.29	0.16	0.33
Adolescents	Germany	EsKiMo	393	0.15	0.37	0.20	0.44
Adolescents	Germany	National_Nutrition_Survey_II	1,011	0.14	0.35	0.17	0.42
Adolescents	Italy	INRAN_SCAI_2005_06	247	0.09	0.23	0.10	0.25
Adolescents	Latvia	EFSA_TEST	453	0.17	0.36	0.21	0.43
Adolescents	Netherlands	VCPBasis_AVL2007_2010	1,142	0.33	0.66	0.35	0.67
Adolescents	Spain	AESAN_FIAB	86	0.09	0.23	0.12	0.26
Adolescents	Spain	NUT_INK05	651	0.17	0.32	0.20	0.37
Adolescents	Spain	enKid	209	0.15	0.35	0.19	0.38
Adolescents	Sweden	NFA	1,018	0.25	0.49	0.29	0.52
Adolescents	United Kingdom	NDNS-RollingProgramme Years1-3	666	0.19	0.38	0.21	0.40
Adults	Austria	ASNS_Adults	308	0.12	0.26	0.13	0.29
Adults	Belgium	Diet_National_2004	1,292	0.16	0.37	0.17	0.39
Adults	Czech Republic	SISP04	1,666	0.07	0.20	0.11	0.25
Adults	Denmark	DANSDA 2005-08	1,739	0.07	0.17	0.08	0.20
Adults	Finland	FINDIET2012	1,295	0.10	0.25	0.12	0.27
Adults	France	INCA2	2,276	0.09	0.19	0.10	0.21
Adults	Germany	National_Nutrition_Survey_II	10,419	0.11	0.27	0.13	0.30
Adults	Hungary	National_Repr_Surv	1,074	0.04	0.13	0.08	0.19
Adults	Ireland	NANS_2012	1,274	0.09	0.20	0.10	0.21
Adults	Italy	INRAN_SCAI_2005_06	2,313	0.05	0.13	0.05	0.14
Adults	Latvia	EFSA_TEST	1,271	0.09	0.20	0.12	0.25
Adults	Netherlands	VCPBasis_AVL2007_2010	2,057	0.17	0.38	0.18	0.39
Adults	Romania	Dieta_Pilot_Adults	1,254	0.04	0.10	0.06	0.15
Adults	Spain	AESAN	410	0.09	0.21	0.10	0.24
Adults	Spain	AESAN_FIAB	981	0.07	0.16	0.08	0.19
Adults	Sweden	Riksmaten 2010	1,430	0.12	0.25	0.14	0.27
Adults	United Kingdom	NDNS-RollingProgramme Years1-3	1,266	0.11	0.24	0.12	0.25
The elderly	Austria	ASNS_Adults	92	0.09	0.19	0.10	0.19
The elderly	Belgium	Diet_National_2004	1,215	0.11	0.26	0.12	0.27
The elderly	Denmark	DANSDA 2005-08	286	0.04	0.11	0.06	0.13
The elderly	Finland	FINDIET2012	413	0.07	0.18	0.09	0.20
The elderly	France	INCA2	348	0.06	0.13	0.07	0.15
The elderly	Germany	National_Nutrition_Survey_II	2,496	0.08	0.19	0.10	0.22
The elderly	Hungary	National_Repr_Surv	286	0.03	0.09	0.06	0.12
The elderly	Ireland	NANS_2012	226	0.06	0.15	0.07	0.17
The elderly	Italy	INRAN_SCAI_2005_06	518	0.03	0.09	0.04	0.10
The elderly	Netherlands	VCP-Elderly	739	0.11	0.23	0.12	0.24
The elderly	Netherlands	VCPBasis_AVL2007_2010	173	0.12	0.23	0.13	0.24

Population groups	Country	Survey	Number of subjects	Current MPLs		Current MPLs + proposed extension of uses	
				Mean	P95	Mean	P95
The elderly	Romania	Dieta_Pilot_Adults	128	0.02	0.06	0.04	0.11
The elderly	Sweden	Riksmaten 2010	367	0.11	0.20	0.12	0.23
The elderly	United Kingdom	NDNS-RollingProgrammeYears1-3	305	0.10	0.19	0.10	0.20

MPL: maximum permitted level; bw: body weight.

Appendix B – Main food categories contributing to exposure to lycopene (E 160d) using the current MPLs and the current MPLs + the proposed extension of use levels

Population groups	Food category number	Food category name	Current MPL			Current MPLs + the proposed extension of uses		
			N surveys contributing > 5%	Min (%)	Max (%)	N surveys contributing > 5%	Min (%)	Max (%)
Infants	01.4	Flavoured fermented milk products including heat-treated products	6	8.9	59.7	6	8.8	42.2
Infants	04.2	Processed fruit and vegetables	3	13.5	54.4	3	11.7	54.2
Infants	07.2	Fine bakery wares	4	5.9	63.1	3	8.6	57.6
Infants	08.3	Meat products				4	5.7	26.9
Infants	09.1.1	Unprocessed fish	2	8.5	15.5	2	8.5	15.5
Infants	12.5	Soups and broths	2	6.1	65.1	2	5.7	65.1
Infants	12.6	Sauces	4	5.1	16.2	4	5.0	16.1
Infants	14.1.4	Flavoured drinks	3	5.9	26.9	3	5.5	23.4
Infants	15.1	Potato-, cereal-, flour- or starch-based snacks	2	5.2	5.6			
Infants	16	Desserts excluding products covered in category 1, 3 and 4	3	7.8	13.9	3	6.8	13.1
Toddlers	01.4	Flavoured fermented milk products including heat-treated products	10	8.4	77.8	10	7.1	73.2
Toddlers	03	Edible ices	2	5.1	10.3	1	7.0	7.0
Toddlers	04.2	Processed fruit and vegetables	1	5.8	5.8	1	5.6	5.6
Toddlers	07.2	Fine bakery wares	9	6.3	51.5	8	8.2	43.6
Toddlers	08.2	Meat preparations as defined by Regulation (EC) No 853/2004				1	6.1	6.1
Toddlers	08.3	Meat products				8	5.8	28.1
Toddlers	09.2	Processed fish and fishery products including molluscs and crustaceans	3	6.1	6.7	3	5.8	5.9
Toddlers	12.5	Soups and broths	4	5.9	12.9	4	5.2	12.3
Toddlers	12.6	Sauces	4	5.7	12.1	4	5.4	10.8
Toddlers	12.9	Protein products, excluding products covered in category 1.8	1	11.2	11.2	1	10.7	10.7

Population groups	Food category number	Food category name	Current MPL			Current MPLs + the proposed extension of uses		
			N surveys contributing > 5%	Min (%)	Max (%)	N surveys contributing > 5%	Min (%)	Max (%)
Toddlers	14.1.4	Flavoured drinks	7	13.9	35.7	7	9.5	30.2
Toddlers	15.1	Potato-, cereal-, flour- or starch-based snacks	1	7.1	7.1	1	6.0	6.0
Toddlers	16	Desserts excluding products covered in category 1, 3 and 4	7	5.5	16.7	6	6.9	14.2
Children	01.4	Flavoured fermented milk products including heat-treated products	16	6.9	51.2	16	5.8	40.4
Children	03	Edible ices	13	5.9	17.1	12	5.1	14.1
Children	05.2	Other confectionery including breath freshening microsweets	5	5.5	10.2	3	5.1	7.7
Children	07.2	Fine bakery wares	16	11.0	43.6	16	10.0	41.0
Children	08.3	Meat products				16	5.9	23.0
Children	09.2	Processed fish and fishery products including molluscs and crustaceans	1	10.8	10.8	1	9.6	9.6
Children	12.5	Soups and broths	5	6.6	33.9	5	5.6	27.8
Children	12.6	Sauces	8	5.7	10.6	8	5.3	9.3
Children	14.1.4	Flavoured drinks	18	7.9	41.8	18	6.7	33.1
Children	15.1	Potato-, cereal-, flour- or starch-based snacks	2	6.4	6.5	1	5.5	5.5
Children	16	Desserts excluding products covered in category 1, 3 and 4	8	5.4	14.7	7	6.1	12.9
Adolescents	01.4	Flavoured fermented milk products including heat-treated products	14	5.1	37.5	11	6.6	32.3
Adolescents	03	Edible ices	7	5.3	17.3	5	5.1	15.6
Adolescents	05.2	Other confectionery including breath freshening microsweets	4	5.5	9.3	3	5.3	7.1
Adolescents	05.3	Chewing gum	2	6.6	8.8	2	5.7	7.6
Adolescents	07.2	Fine bakery wares	15	11.6	37.9	15	9.7	34.1
Adolescents	08.3	Meat products				16	5.4	22.9
Adolescents	09.2	Processed fish and fishery products including molluscs and crustaceans	3	5.8	8.3	2	6.5	7.4

Population groups	Food category number	Food category name	Current MPL			Current MPLs + the proposed extension of uses		
			N surveys contributing > 5%	Min (%)	Max (%)	N surveys contributing > 5%	Min (%)	Max (%)
Adolescents	12.5	Soups and broths	5	6.2	31.1	5	5.3	24.8
Adolescents	12.6	Sauces	9	7.4	18.3	9	6.8	15.3
Adolescents	14.1.4	Flavoured drinks	17	16.7	53.9	17	13.4	46.3
Adolescents	15.1	Potato-, cereal-, flour- or starch-based snacks	4	5.1	7.2	3	5.1	7.0
Adolescents	16	Desserts excluding products covered in category 1, 3 and 4	4	6.4	11.4	4	5.4	10.0
Adults	01.4	Flavoured fermented milk products including heat-treated products	15	6.3	24.1	15	5.4	20.6
Adults	03	Edible ices	2	6.6	12.4	2	5.3	10.5
Adults	05.2	Other confectionery including breath freshening microsweets	1	5.7	5.7			
Adults	05.3	Chewing gum	1	7.2	7.2	1	5.8	5.8
Adults	07.2	Fine bakery wares	17	6.1	36.4	16	5.3	31.0
Adults	08.3	Meat products				17	6.0	47.5
Adults	09.1.1	Unprocessed fish	1	6.8	6.8	1	5.6	5.6
Adults	09.2	Processed fish and fishery products including molluscs and crustaceans	5	5.0	11.4	3	8.3	9.7
Adults	12.5	Soups and broths	8	6.0	41.1	8	5.5	32.0
Adults	12.6	Sauces	11	5.5	24.0	10	7.7	21.3
Adults	12.9	Protein products, excluding products covered in category 1.8	1	5.4	5.4			
Adults	14.1.4	Flavoured drinks	17	9.0	64.1	17	7.0	36.5
Adults	15.1	Potato-, cereal-, flour- or starch-based snacks	1	12.4	12.4	1	7.7	7.7
Adults	16	Desserts excluding products covered in category 1, 3 and 4	4	7.2	12.6	4	6.8	10.3
The elderly	01.4	Flavoured fermented milk products including heat-treated products	12	7.2	23.8	11	6.8	19.7
The elderly	03	Edible ices	2	9.8	10.5	2	7.3	9.2
The elderly	04.2	Processed fruit and vegetables				2	5.2	6.0

Population groups	Food category number	Food category name	Current MPL			Current MPLs + the proposed extension of uses		
			N surveys contributing > 5%	Min (%)	Max (%)	N surveys contributing > 5%	Min (%)	Max (%)
The elderly	07.2	Fine bakery wares	14	11.1	42.2	14	8.2	37.0
The elderly	08.3	Meat products				14	5.8	50.1
The elderly	09.1.1	Unprocessed fish	4	6.9	8.5	4	5.8	7.4
The elderly	09.2	Processed fish and fishery products including molluscs and crustaceans	5	5.6	10.6	4	6.3	9.3
The elderly	12.5	Soups and broths	8	10.3	36.5	8	9.5	33.7
The elderly	12.6	Sauces	11	6.0	17.4	10	5.6	14.8
The elderly	14.1.4	Flavoured drinks	11	5.7	53.8	10	5.8	26.8
The elderly	15.1	Potato-, cereal-, flour- or starch-based snacks	1	6.3	6.3			
The elderly	16	Desserts excluding products covered in category 1, 3 and 4	6	6.2	13.9	6	5.3	12.7

MPL: maximum permitted level.

Appendix C – Number and percentage of food products labelled with lycopene (E 160d) out of the total number of food products present in the Mintel GNPD per food subcategory between 2012 and 2017^(a)

Mintel subcategory ^(b)	Total number of products	Products labelled with lycopene (E 160d)	
		Number	%
Meal Replacements & Other Drinks	1,790	58	3.2
Meat Substitutes	3,023	28	0.9
Vitamins & Dietary Supplements	8,726	51	0.6
Fruit/Flavoured Still Drinks	3,104	7	0.2
Baby Fruit Products, Desserts & Yogurts	1,811	4	0.2
Flavoured Milk	1,523	3	0.2
RTD (Iced) Tea	1,978	3	0.2
Shelf-Stable Desserts	3,079	4	0.1
Oils	5,224	4	0.1
Carbonated Soft Drinks	6,551	5	0.1
Total sample	36,809	186	0.5 ^(c)

MPL: maximum permitted level; bw: body weight.

(a): Year 2017 is not a complete year (up to 18/9/2017).

(b): According to the Mintel food categorisation.

(c): In total, around 0.5% of the foods available on the Mintel GNPD are labelled with lycopene (E 160d) between 2012 and 2017.