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# FOOD STANDARDS AGENCY CONSULTATION

## Title: The Food Additives (England) (Amendment) (No.2) Regulations 2011

### CONSULTATION SUMMARY PAGE

| Date consultation launched: | Closing date for responses: |
|---|---|
| 23 March 2011 | 20 April 2011 |

**Who will this consultation be of most interest to?**

**Manufacturers of food colours, food manufacturers using food colours and enforcement authorities.**

**What is the subject of this consultation?**

**National Regulations relating to England to implement European Commission Directive 2011/3/EU. This Directive revises the purity criteria for the sole source of lycopene previously permitted for use (obtained from tomatoes) and permits the use of, and sets purity criteria for, two additional sources of lycopene (synthetic lycopene and lycopene from the fungus Blakeslea trispora).**

**What is the purpose of this consultation?**

**To provide stakeholders with an opportunity to comment on the provisions of the Commission Directive and on the draft Food Additives (England) (Amendment) (No.2) Regulations 2011, which would implement the Directive in England.**

**Responses to this consultation should be sent to:**


**Name : Nasreen Shah**
**Division/Branch : Chemical Safety Division**
**FOOD STANDARDS AGENCY**
**Tel: 020 7276 8553**
**Fax: 020 7276 8446**

**Postal address:**
**Room 5B, Aviation House,**
**125 Kingsway, London,**
**WC2B 6NH.**
**Email:** nasreen.a.shah@foodstandards.gsi.gov.uk


| Is an Impact Assessment included with this consultation? | Yes ☐ | No ☒ See Annex A for reason. |
|---|---|---|

INVESTOR IN PEOPLE

**If you would prefer to receive future FSA consultations by e-mail, or if** you no longer wish to receive information on this subject please notify the named person in this consultation.

POSITIVE ABOUT DISABLED PEOPLE

# The Food Additives (England) (Amendment) (No.2) Regulations 2011

## DETAIL OF CONSULTATION

### Introduction

1. In 2007, the European Food Safety Authority (EFSA) assessed available information on the safety of the use of lycopene as a food colour from all sources, specifically (a) solvent extraction of the natural strains of red tomatoes, (b) synthetic lycopene and (c) lycopene from Blakeslea trispora.

2. In its opinion, published in early 2008, EFSA reaffirmed the safety of lycopene from tomatoes for use as a food colour and gave a favourable opinion on the safety of the other two sources for such use.

3. Amendments are necessary to the purity criteria set down in EU legislation for lycopene obtained from tomatoes to reflect changes in industry practice and changes to international standards.

### The European Commission Directive

4. In July 2009, the European Commission issued a proposal to make amendments to Directive 2008/128/EC (purity criteria for food colours) in order to (a) adjust the purity criteria for lycopene obtained from tomatoes, and (b) set purity criteria for, and permit the use of, the two sources of lycopene on which EFSA had given a favourable opinion.

5. The Commission's proposal was adopted by Qualified Majority in the EU Standing Committee on the Food Chain and Animal Health (SCOFCAH) on 10 September 2010 and was published in the Official Journal of the EU as Commission Directive 2011/3/EU on 18 January 2011.

### Purpose of Consultation

6. The purpose of this consultation is to provide stakeholders with an opportunity to comment on the provisions of the Commission Directive and on the draft Food Additives (England) (Amendment) (No.2) Regulations 2011, which would implement the Directive in England. Separate consultations will be carried out in Scotland, Wales and Northern Ireland in due course on draft Regulations relating to those parts of the United Kingdom.

### Draft Regulations

7. The draft Food Additives (England) (Amendment) (No.2) Regulations 2011 are attached at Annex B. These Regulations would implement the Commission Directive by making amendments to the Food Additives (England) Regulations 2009 (S.I. 2009/3238), in accordance with the Government's Guiding Principles for EU Legislation, so as to:

    - Implement the permissive element of the Directive (the two new sources of lycopene) as soon as practicable;

- Implement the restrictive element (the revised purity criteria for lycopene from tomatoes) on the latest date for implementation stipulated in the Directive of 1 September 2011.

## Proposals

**Key proposal:**

- **Implementation of the Commission Directive 2011/3/EU in England by means of national Regulations to amend the Food Additives (England) Regulations 2009 (S.I. 2009/3238) which will:**
  - **Implement the permissive element of the Directive (the two new sources of lycopene) as soon as practicable;**
  - **Implement the restrictive element (the revised purity criteria for lycopene from tomatoes) on the latest date for implementation stipulated in the Directive of 1 September 2011.**

## Consultation Process / Impact

8. The FSA consulted industry whilst EU negotiations on the Directive were ongoing. This consultation revealed that industry can already comply with the revised specification for lycopene from tomatoes. Permitting the use of the two additional sources of lycopene will be beneficial to industry as it will be able to use these sources for the first time.

9. As there would be no incremental impact on UK industry arising from the implementation of the Directive, the FSA has not prepared an Impact Assessment (IA) on this occasion. Should this consultation bring to light any new impacts, the FSA will reconsider the need for an IA.

10. Given the minimal impact and the intention to implement the permissive elements of the Directive as soon as practicable, this consultation is being conducted for a shortened period of 4 weeks.

**Questions asked in this consultation**

**Q1:** Do you agree with the key proposals detailed above?

**Q2:** What are the costs and benefits associated with the key proposals?

**Q3:** Do you think that the Regulations, if enacted as drafted, would achieve these aims?

## Other relevant documents

11. Commission Directive 2011/3/EU of 17 January 2011 amending Directive 2008/128/EC laying down specific purity criteria on colours for use in foodstuffs. This can be found at the following location on the European Union website at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:013:0059:0063:EN:PDF

## Responses

12. Responses are requested by close of business on Friday 20 April 2011. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

13. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

**Yours,**

**Nasreen Shah**
**Regulation and Business Support Team**
**Chemical Safety Division**

**Enclosed**

**Annex A: Standard Consultation Information**

**Annex B: Draft Statutory Instrument**

**Annex C: Commission Directive 2011/3/EU**

**Annex D: List of interested parties**

## Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

## Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at **http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc**. Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

## Further information

5. A list of interested parties to whom this letter is being sent appears in Annex B. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.

7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: **http://www.berr.gov.uk/files/file47158.pdf**. The Consultation Criteria from that Code should be included in each consultation and they are listed below:

### The Seven Consultation Criteria

**Criterion 1** - **When to consult**
*Formal consultation should take place at a stage when there is scope to influence the policy outcome.*

**Criterion 2 - Duration of consultation exercises**
*Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.*

**Criterion 3 - Clarity of scope and impact**
*Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.*

**Criterion 4 - Accessibility of consultation exercises**
*Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.*

**Criterion 5 - The burden of consultation**
*Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.*

**Criterion 6 - Responsiveness of consultation exercises**
*Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.*

**Criterion 7 - Capacity to consult**
*Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.*

8. Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible*. This consultation is not being held for a full 12 weeks. It is instead being held for a shortened period of 4 weeks due to the minimal impact identified through earlier consultation and the intention to implement the permissive elements of the Commission Directive as soon as practicable, which may benefit industry.

9. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. As the consultation revealed no incremental impact on UK industry arising from the implementation of the Directive, the FSA does not intend to produce an Impact Assessment. However, if the formal consultation identifies any new impacts it will reconsider the need for an Impact Assessment.

10. For details about the consultation process (not about the content of this consultation) please contact: **Food Standards Agency Consultation Co-ordinator**, Room 2B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

## Comments on the consultation process itself

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at: **http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc**.

12. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at: **http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc**. The questionnaire can also be used to update us about your existing contact details.

STATUTORY INSTRUMENTS

# 2011 No. 0000

# FOOD, ENGLAND

# The Food Additives (England) (Amendment) (No.2) Regulations 2011

*Made - - - -* *2011*

*Laid before Parliament* *2011*

*Coming into force in accordance with regulation 3*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a) and (f),17(1) and 48(1) of the Food Safety Act 1990(**a**) and now vested in him(**b**).

In accordance with section 48(4A) of that Act, he has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**c**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title**

**1.** These Regulations may be cited as the Food Additives (England) (Amendment) (No.2) Regulations 2011.

(**a**) 1990 c. 16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999 Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.

(**b**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28). Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

(**c**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p14).

**Amendment of the Food Additives (England) Regulations 2009**

**2.**—(1) The Food Additives (England) Regulations 2009(**a**) are amended in accordance with paragraph (2).

(2) In paragraph (1) of regulation 2 (interpretation), at the end of the definition of "Directive 08/128" add the expression "as amended by Commission Directive 2011/3/EU amending Directive 2008/128/EC laying down specific purity criteria on colours for use in foodstuffs;".

**Commencement**

**3.**—(1) These Regulations come into force —

(a) as regards the entries for synthetic lycopene and lycopene from Blakeslea trispora in sections (i) and (iii) respectively of the Annex to Directive 2011/3/EU, [*insert date when known*]; and

(b) as regards the entries for lycopene from red tomatoes in section (ii) of that Annex, 1st September 2011.

(2) In this regulation Directive 2011/3/EU means Commission Directive 2011/3/EU amending Directive 2008/128/EC laying down specific purity criteria on colours for use in foodstuffs(**b**).

Signed by authority of the Secretary of State for Health

*Name*
Parliamentary Under Secretary of State
Department of Health

Date

(**a**) S.I. 2009/3238. These Regulations were amended by S.I. 2011/258.
(**b**) OJ No. L13, 18.1.2011, p.59.

# DIRECTIVES

## COMMISSION DIRECTIVE 2011/3/EU

**of 17 January 2011**

**amending Directive 2008/128/EC laying down specific purity criteria on colours for use in foodstuffs**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [1], and in particular Article 30(5) thereof,

After consulting the European Food Safety Authority (EFSA),

Whereas:

(1) Commission Directive 2008/128/EC [2] sets out the specific purity criteria concerning colours for use in foodstuffs, which colours are mentioned in European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs [3].

(2) Under Article 30(4) of Regulation (EC) No 1333/2008 specifications of the food additives covered under paragraphs 1 to 3 of that Article (which include also additives authorised under Directive 94/36/EC) shall be adopted, in accordance with 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 [4], at the moment those food additives are entered in the Annexes in accordance with those paragraphs.

(3) Since the lists have not yet been drawn up, and in order to ensure that the modification of the Annexes to Directive 94/36/EC pursuant to Article 31 of Regulation (EC) No 1333/2008 is effective and that additives so authorised comply with safe conditions of use, Directive 2008/128/EC should therefore be amended.

(4) The European Food Safety Authority (hereinafter 'the Authority') has assessed the information on the safety in use of lycopene as a food colour from all sources in its opinion of 30 January 2008 [5]. The sources that were considered were the following: (a) E160d Lycopene obtained by solvent extraction of the natural strains of red tomatoes (*Lycopersicon esculentum* L.) with subsequent removal of the solvent, (b) synthetic lycopene and (c) lycopene from *Blakeslea trispora*.

(5) Current legislation lays down specifications only for lycopene of red tomatoes and needs to be modified respectively by including the other two sources. Specifications of lycopene extracted from red tomatoes need also to be updated. Dichloromethane does not need to be listed in the list of the extraction solvents, as it is not used any more for lycopene of red tomatoes, according to the information received from stakeholders. Maximum limit for lead needs to be lowered due to safety reasons, and the reference on heavy metals is too generic and not relevant any more. In addition the reference on natural strains needs to be updated according to Regulation (EC) No 1829/2003 of the European Parliament and of the Council [6].

(6) Dichloromethane (methylene chloride) is being reported to be used for manufacturing ready-to-sale formulations of lycopene, mentioned also in the Authority's opinion

[1] OJ L 354, 13.12.2008, p. 16.
[2] OJ L 6, 10.1.2009, p. 20.
[3] OJ L 237, 10.9.1994, p. 13.
[4] OJ L 354, 31.12.2008, p. 1.
[5] Scientific opinion of the panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the European Commission to provide a scientific opinion on the safety of use of 1. lycopene obtained from a fermentation process with *Blakeslea trispora* as a food colour in the food categories and use levels as proposed by the applicant and 2. synthetic lycopene as a food colour in the food categories listed in Annex III and Annex V, part 2 to Directive 94/36/EC on food colours for use in foodstuffs, 3. taking into account the various requests concerning lycopene currently under consideration including the re-evaluation of lycopene from tomatoes as part of the systematic re-evaluation of all food colours. The EFSA Journal (2008) 674, 1-66.
[6] OJ L 268, 18.10.2003, p. 1.

on Safety of 'Lycopene Cold Water Dispersible Products from *Blakeslea trispora*' of 4 December 2008 [1]. Similar products are produced also from synthetic lycopene, as mentioned in the Authority's opinion on safety of Synthetic Lycopene of 10 April 2008 [2]. As the Authority evaluated this specific use, it is necessary to authorise this use by the same residual levels that were considered during the evaluation.

(7) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius drafted by the Joint Expert Committee on Food Additives (JECFA). In particular, the specific purity criteria need to be adapted to reflect the limits for individual heavy metals of interest, where appropriate.

(8) Directive 2008/128/EC should therefore be amended accordingly.

(9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

The Annex I to Directive 2008/128/EC is amended in accordance with the Annex to this Directive.

*Article 2*

**Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 September 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 17 January 2011.

*For the Commission*
*The President*
José Manuel BARROSO

[1] Scientific opinion of the panel on Dietetic Products, Nutrition and Allergies on a request from European Commission to carry out an additional assessment for 'Lycopene Cold Water Dispersible Products (CWD) from *Blakeslea Trispora*' as a food ingredient in the context of Regulation (EC) No 258/97. The EFSA Journal (2008) 893, 1-15.

[2] Scientific opinion of the panel on Dietetic Products, Nutrition and Allergies on a request from the European Commission on safety of synthetic Lycopene. The EFSA Journal (2008) 676, 1-25.

*ANNEX*

In Annex I to Directive 2008/128/EC the entry on E 160 d is replaced by the following:

'E 160 D LYCOPENE

| | |
|---|---|
| (i) ***synthetic lycopene*** | |
| **Synonyms** | Lycopene from chemical synthesis |
| **Definition** | Synthetic lycopene is a mixture of geometric isomeres of lycopenes and is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists predominantly of all-trans-lycopene together with 5-cis-lycopene and minor quantities of other isomers. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water- soluble powder. |
| Colour Index No | 75125 |
| EINECS | 207-949-1 |
| Chemical name | Ψ,Ψ-carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene |
| Chemical formula | $C_{40}H_{56}$ |
| Molecular weight | 536,85 |
| Assay | Not less than 96 % total lycopenes (not less than 70 % all-trans-lycopene)<br>$E_{1\ cm}^{1\ \%}$ at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450 |
| **Description** | Red crystalline powder |
| **Identification** | |
| Spectrophotometry | A solution in hexane shows an absorption maximum at approximately 470 nm |
| Test for carotenoids | The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid |
| Solubility | Insoluble in water, freely soluble in chloroform |
| Properties of 1 % solution in chloroform | Is clear and has intensive red-orange colour |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (40 °C, 4 h at 20 mm Hg) |
| Apo-12'-lycopenal | Not more than 0,15 % |
| Triphenyl phosphine oxide | Not more than 0,01 % |
| Solvent residues | Methanol not more than 200 mg/kg,<br>Hexane, Propan-2-ol: Not more than 10 mg/kg each.<br>Dichloromethane: Not more than 10 mg/kg (in commercial preparations only) |
| Lead | Not more than 1 mg/kg |

| | |
|---|---|
| (ii) ***from red tomatoes*** | |
| **Synonyms** | Natural Yellow 27 |
| **Definition** | Lycopene is obtained by solvent extraction of red tomatoes (*Lycopersicon esculentum* L.) with subsequent removal of the solvent. Only the following solvent may be used:<br>carbon dioxide, ethyl acetate, acetone, propan-2-ol, methanol, ethanol, hexane. The major colouring principle of tomatoes is lycopene, minor amounts of other carotenoid pigments may be present. Besides the colour pigments the product may contain oil, fats, waxes and flavour components naturally occurring in tomatoes. |
| Colour Index No | 75125 |
| EINECS | 207-949-1 |
| Chemical name | Ψ,Ψ-carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene |
| Chemical formula | $C_{40}H_{56}$ |
| Molecular weight | 536,85 |
| Assay | $E_{1\ cm}^{1\ \%}$ at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450.<br>Content not less than 5 % total colouring matters |
| **Description** | Dark red viscous liquid |
| **Identification** | |
| Spectrophotometry | Maximum in hexane at ca 472 nm |
| **Purity** | |
| Solvent residues | Propane-2-ol<br>Hexane<br>Acetone<br>Ethanol<br>Methanol<br>Ethylacetate<br>Not more than 50 mg/kg, singly or in combination |
| Sulphated ash | Not more than 1 % |
| Mercury | Not more than 1 mg/kg |
| Cadmium | Not more than 1 mg/kg |
| Arsenic | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |
| (iii) ***from* Blakeslea trispora** | |
| **Synonyms** | Natural Yellow 27 |
| **Definition** | Lycopene from *Blakeslea trispora* is extracted from the fungal biomass and purified by crystallisation and filtration. It consists predominantly of all-trans-lycopene. It also contains minor quantities of other carotenoids. Isopropanol and isobutyl acetate are the only solvents used in the manufacture. Commercial lycopene preparations intended for use in food are formulated as suspensions in edible oils or water-dispersible or water-soluble powder. |

| | |
|---|---|
| Colour Index No | 75125 |
| EINECS | 207-949-1 |
| Chemical name | Ψ,Ψ-carotene, all-trans-lycopene, (all-E)-lycopene, (all-E)-2,6,10,14,19,23,27,31-octamethyl-2,6,8,10,12,14,16,18,20,22,24,26,30-dotriacontatridecaene |
| Chemical formula | $C_{40}H_{56}$ |
| Molecular weight | 536,85 |
| Assay | Not less than 95 % total lycopenes and not less than 90 % all-trans-lycopene of all colouring matters<br>$E_{1\ cm}^{1\ \%}$ at 465 - 475 nm in hexane (for 100 % pure all-translycopene) is 3 450 |
| **Description** | Red crystalline powder |
| **Identification** | |
| Spectrophotometry | A solution in hexane shows an absorption maximum at approximately 470 nm |
| Test of carotenoids | The colour of the solution of the sample in acetone disappears after successive additions of a 5 % solution of sodium nitrite and 1N sulphuric acid |
| Solubility | Insoluble in water, freely soluble in chloroform |
| Properties of 1 % solution in chloroform | Is clear and has intensive red-orange colour |
| **Purity** | |
| Loss on drying | Not more than 0,5 % (40 °C, 4 h at 20 mm Hg) |
| Other carotenoids | Not more than 5 % |
| Solvent residues | Propan-2-ol: Not more than 0,1 %<br>Isobutyl acetate: Not more than 1,0 %<br>Dichloromethane: Not more than 10 mg/kg (in commercial preparations only) |
| Sulphated ash | Not more than 0,3 % |
| Lead | Not more than 1 mg/kg' |

## LIST OF INTERESTED PARTIES ANNEX D

British Retail Consortium
The Food Additives & Ingredients Association
Natcol