

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**Agenda Item 10**

**CX/FA 08/40/15 Add.1**

April 2008

(Original language only)

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Fortieth Session

Beijing, China, 21-25 April 2008

#### PRIORITY LIST OF FOOD ADDITIVES PROPOSED FOR EVALUATION BY JECFA

#### NEW REQUESTS AND INFORMATION ON COMPOUNDS ALREADY INCLUDED IN THE PRIORITY LIST

(in response to CL 2007/27-FA)

The following comments have been received from the following Codex Members and Observers:

European Community, Israel and Switzerland

#### European Community:

Following the conclusions in the 68<sup>th</sup> report of JECFA, on exposure assessment, the European Community and its Member States (ECMS) would request that JECFA reconsider the potential genotoxicity of alpha-beta unsaturated substances and their precursors evaluated in earlier reports. The list with the JECFA numbers of the substances is attached.

In the default evaluation procedure, JECFA employs the maximized survey-derived intake (MSDI) method as a measure of dietary exposure. The MSDI provides an estimate of the mean exposure of consumers to a flavouring agent. The European Community and its Member States appreciate the application of the SPET approach.

In its 68<sup>th</sup> report of JECFA explored an additional new method of dietary exposure assessment (since termed the single-portion exposure technique or SPET) based on the daily consumption of a single portion of food containing the flavouring agent.

The SPET was used to estimate dietary exposure for 57 flavouring agents. It was concluded that in general, the estimated dietary exposure using the SPET was up to several orders of magnitude higher than that calculated by the MSDI for any of the three geographic regions for which production volume data were available (Europe, Japan and USA).

The Committee however concluded that the MSDI and SPET dietary exposure estimates provide different and complementary information and that it would not be necessary to re-evaluate flavouring agents that have already been assessed using the Procedure.

The European Community and its Member States would like to bring to the attention of the Committee the conclusions on genotoxicity in the report of the 63<sup>rd</sup> JECFA (WHO food additives series 54, page 374) on *Aliphatic, Linear alpha-beta unsaturated Aldehydes, Acids and related Alcohols, Acetals and Esters*. This concluded that such alpha-beta unsaturated components are genotoxic but that at low concentrations, such as those resulting from intake of flavourings substances, alpha – beta unsaturated aldehydes are rapidly

metabolised in the high capacity beta-oxidation pathway and that there is no convincing evidence that alpha-beta-unsaturated aldehydes exhibit significant genotoxic potential in vivo.

The European Community and its Member States would like JECFA to reconsider this conclusion taking into account that for most of the substances the exposure assessment based on the SPET may be orders of magnitude higher than that calculated by MSDI and whether a threshold mechanism for genotoxicity can be assigned.

**List of substances for which the European Community and its Member States would request to reconsider potential genotoxicity:**

Evaluation of certain food additives and contaminants: Fifty-fifth report of the Joint FAO/WHO expert Committee on food additives, (2000)

JECFA numbers: 647, 648, 656, 650, 652, 649, 651, 654, 653, 655, 673, 678, 677, 681, 682, 687, 689, 688, 686, 685, 684, 743, 740, 742, 741, 739, 751, 451, 450

Evaluation of certain food additives and contaminants: Fifty-seventh report of the Joint FAO/WHO expert Committee on food additives, (2001)

JECFA numbers: 948, 944

Evaluation of certain food additives and contaminants: Fifty-ninth report of the Joint FAO/WHO expert Committee on food additives, (2002)

JECFA numbers: 973, 974, 975, 977, 979, 980, 981, 982, 983, 985, 1020, 1022, 1050, 1051, 1098, 1105, 1106, 1107, 1115, 1111, 1114, 1112, 1113, 1139, 1134, 1149, 1140, 1141, 1124, 1125, 1129, 1131, 1126, 1127, 1132, 1130, 1133, 1135, 1136, 1138, 1152, 1150, 1151, 1153, 1148, 1147.

Evaluation of certain food additives and contaminants: Sixty-first report of the Joint FAO/WHO expert Committee on food additives, (2003)

JECFA numbers: 1163, 1162, 1164, 1172, 1173, 1175, 1179, 1174, 1195, 1196, 1181, 1190, 1184, 1186, 1185, 1182, 1197, 1187, 1189, 1198, 1208, 1216, 1209, 1201, 1214, 1215, 1217, 1227, 1207, 1226, 1223, 1230, 1224, 1200, 1225, 1202, 1228

Evaluation of certain food additives and contaminants: Sixty-third report of the Joint FAO/WHO expert Committee on food additives, (2004)

JECFA numbers: 1306, 1307, 1319, 1354, 1365, 1369, 1374, 1384, 1350, 1363, 1349, 1359, 1364, 1366, 1360, 1362, 1353, 1355, 1378, 1375, 1376, 1381, 1377, 1398, 1403, 1404, 1406, 1405, 1409, 1446, 1449, 1450, 1451, 1456, 1480, 1481, 1482, 1484, 1472, 1473

Evaluation of certain food additives and contaminants: Sixty-fifth report of the Joint FAO/WHO expert Committee on food additives, (2005)

JECFA numbers: 1570, 1571, 1574

**Israel:**

The Government of Israel strongly supports the inclusion of Lycopene oleoresin extract from tomatoes in the priority list of the agenda for the forthcoming JECFA 71 session and requests that it be added to Document CX/FA 08/40/15 for consideration at the Codex meeting in Beijing.

Attached for your convenience is a copy of the required form we submitted with our December 6, 2007 letter, specifying the available information about Lycopene oleoresin.

We are aware that lycopene from a number of sources has already been dealt with by the JECFA. Given, however, that tomatoes and tomato products are the richest dietary sources of lycopene, and that they satisfy more than 80 percent of total lycopene intake by the population, it is of special interest to determine the ADI for this anti-oxidant from natural sources.

There are significant differences between natural lycopene (tomato oleoresin) and the synthetic or crystalline additive. Therefore it is our view that the Expert Panel should consider the safe use of tomato oleoresin as a different product, compared to fungal crystalline or synthetic lycopene. As stated in the attached form, we are able to provide the necessary information to the Expert Panel upon request.

The quality, quantity and adequacy of the available data are pertinent to performing an effective risk assessment for Lycopene oleoresin. We believe that JECFA's evaluation is most important in the context of evaluations already undertaken by other international organizations.

### **Information on the Additive to be Evaluated by JECFA**

#### **Lycopene oleoresin extract from tomatoes**

##### **1. Proposal for inclusion submitted by:**

Grisha Deitch  
Commissioner of Standardization  
Ministry of Industry, Trade and Labor  
Jerusalem, Israel.  
Phone: 972-2-6662296  
Fax: 972-2-6662943

##### **2. Name of compound; trade name(s); chemical name(s):**

Compound: Tomato extract containing lycopene

Trade name: Lyc-O-Mato<sup>®</sup>

Chemical name: Lyc-O-Mato<sup>®</sup> does not have a chemical name as it is a tomato oleoresin containing lycopene. The Lycopene is specified as: (all-trans)-lycopene.

CAS-number: Lyc-O-Mato<sup>®</sup> does not have a CAS number.

The CAS number of the active lycopene is [502-65-8].

Other common names: - Lycopene oleoresin

- Natural tomato extract containing lycopene.

- Lycopene is also referred to as: ΨΨ-carotene.

##### **3. Names and addresses of basic producers:**

LycORed  
Natural Products Industries Ltd  
PO Box 320  
Beer-Sheva  
84102 ISRAEL

##### **4. Has the manufacturer made a commitment to provide data?**

LycORed Natural Products Industries Ltd commits to provide data to support the proposal for inclusion of the lycopene from tomato oleoresin in the list of substances to be evaluated by JECFA.

##### **5. Identification of the manufacturer that will be providing data (Please indicate contact person):**

LycORed  
Natural Products Industries Ltd  
PO Box 320  
Beer-Sheva  
84102 ISRAEL

Attn: Dr Zvi Paster  
Tel: +972-8-9420882  
Cell +972-54-6303789  
Email: zpaster@zahav.net.il

##### **6. Justification for use:**

As a colouring agent and nutrient in foods.

**7. Food products and food categories within the GSFA in which the compound is used, including use level(s):**

Lycopene is currently permitted in the European Union as a food colouring in:

<b>Category number</b>	<b>Category description</b>
01.6.2.2	Rind of ripened cheese
01.6.4	Processed cheese
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)
03.0	Edible ices, including sherbet and sorbet
04.1.2.5	Jams, jellies, marmalades
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5
04.1.2.7	Candied fruit
04.1.2.9	Fruit-based desserts, incl. fruit-flavoured water-based desserts
04.2.2.6	Vegetable, (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5
05.0	Confectionary
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit), and sweet sauces
07.2	Fine bakery wares (sweet, salty, savoury) and mixes
08.4	Edible casings (e.g., sausage casings)
09.2.4.2	Cooked molluscs, crustaceans, and echinoderms
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms
09.3.3	Salmon substitutes, caviar, and other fish roe products
09.3.4	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3
10.4	Egg based desserts
12.5	Soups and broths
12.9	Protein products
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)
13.4	Dietetic formulae for slimming purposes and weight reduction
13.6	Food supplements
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulate drinks
15.0	Ready-to-eat savouries

Use levels 5-15mg/portion

**8. Has the compound been approved for use in 2 or more countries (please identify the countries)?**

Yes, the compound is approved for food additive use as a colour in the European Union, EC specifications E160d. Commission Directive 95/45/EC (26 August 1995). The compound has also GRAS status and is approved as a colour additive by the USFDA (21 CFR part 73. August 26, 2005).

**9. List of data (toxicology, dietary exposure, specifications on chemical identity and purity, analytical methods) available:**

**Toxicology:**

A full spectrum of toxicological studies carried out on tomato lycopene is given in an application for the assessment of Lyc-O-Mato tomato sourced lycopene as a novel food under European Union Regulation

258/97 on Novel Foods and Novel Food Ingredients (2004) and a second application (February 2007). All the data are available on request.

Reported in the applications are studies on lycopene oleoresin from tomatoes, including short-term and sub-chronic toxicity (13 weeks/rats), genotoxicity tests, sensitisation and allergenicity studies, eye and skin irritation studies. In addition there are fourteen human studies using supplementation with lycopene oleoresin where safety end points and safety evaluations were considered. A further four human studies which utilised tomato-based food products also reported on safety end points and safety evaluations.

**Dietary exposure:**

An evaluation of dietary exposure based on European Union data is currently in progress.

**Specifications on chemical identity and purity:**

Tomato lycopene oleoresin for use as a food colorant contains 60-70% lycopene. The remainder of the substance consists of other carotenoids (phytoene, phytofluene,  $\beta$ -carotene), tocopherols, sterols, fatty acids, acylglycerols, water, water soluble matter, phospholipids.

There is appropriate analytical information available on potentially toxic inherent constituents and external contaminants.

Tomato lycopene oleoresin is produced only from ripe tomato pulp. The process is based on conventional, physical unit operations, chemical reactions are not involved and no additives are used. Throughout the process great care is taken to protect lycopene and the other tomato carotenoids from oxidation and therefore their original composition is preserved in the oleoresin.

**Analytical methods:**

Test methods have been developed by LycoRed using HPLC methods for the determination of tomato lycopene in the final product and several food categories. Detailed methods are available on request.

**10. Date on which data could be submitted to JECFA:**

On request.

**Switzerland:**

Switzerland has the honor to submit to you a request for the evaluation by JECFA at its 40<sup>th</sup> Meeting (2008), of Ferrous Ammonium Phosphate (FAP)

Please find below the relevant information:

**1. Proposal for inclusion submitted by:**

Switzerland

**2. Name of compound; trade name(s); chemical name(s)**

Ferrous ammonium phosphate

Phosphoric acid, ammonium iron (2+) salt (1:1:1)

**3. Name and addresses of basic producers**

Dr. P. Lohmann GmbH

Postfach 1220

D-31857 Emmerthal

Germany

**4. Has the manufacture made a commitment to provide data?**

Yes

**5. Identification of the manufacturer that will be providing data (contact person)**

Mr. Klaus Brockhausen, (k.brockhausen@lohmann4minerals.com)

Dr. P. Lohmann GmbH  
Postfach 1220  
D-31857Emmerthal, Germany

**6. Justification for use**

Food Fortification with Iron

**7. Food products and food categories within GSFA in which the compound is used, including use level(s)**

Product categories: Cocoa-Malt Beverages, Full Cream Milk Powder, Bouillon, Instant Noodle Preparations

Intended use levels: 33.3mg/100g (Beverages) - 240mg/100g (Bouillon)

**8. Has the compound been approved for use in 2 or more countries**

Not yet approved in any country. Applications will be made during 2008 to US FDA and EU EFSA

**9. List of data (toxicology, dietary, exposure, specifications on chemical identity and purity, analytical methods) available.**

A dossier containing data in relation to all of these parameters will be available for JECFA (e.g. Chemical Specification, Manufacturing Process, Methods of analysis in Food, Dietary Exposure and Intended Use Levels, Bioavailability, Toxicological data)

**10. Date on which data could be submitted to JECFA**

September 2008