



**Food and Agriculture Organization
of the United Nations**



**World Health
Organization**

**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Seventy-first meeting
Geneva, 16–24 June 2009**

SUMMARY AND CONCLUSIONS
Issued 1 July 2009

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Geneva, Switzerland, from 16 to 24 June 2009. The purpose of the meeting was to evaluate certain food additives.

Mrs I. Meyland, National Food Institute, Technical University of Denmark, served as Chairperson, and Dr A. Mattia, Center for Food Safety and Applied Nutrition, United States Food and Drug Administration, served as Vice-Chairperson.

Dr A. Wennberg, Nutrition and Consumer Protection Division, Food and Agriculture Organization of the United Nations, and Dr A. Tritscher, Department of Food Safety, Zoonoses and Foodborne Diseases, World Health Organization, served as Joint Secretaries.

The present meeting was the seventy-first in a series of similar meetings. The tasks before the Committee were (a) to elaborate principles governing the evaluation of food additives, (b) to evaluate certain food additives and (c) to review and prepare specifications for selected food additives.

The report of the meeting will be published in the WHO Technical Report Series. Its presentation will be similar to that of previous reports—namely, general considerations, comments on specific substances, and recommendations for future work. An annex will include detailed tables (similar to the tables in this report) summarizing the main conclusions of the Committee in terms of acceptable daily intakes (ADIs) and other toxicological and safety recommendations. Information on the specifications for the identity and purity of certain food additives examined by the Committee will also be included.

The participants in the meeting are listed in Annex 1. Further information required or desired and recommendations are listed in Annex 2. Items of a general nature that the Committee would like to disseminate quickly are included in Annex 3.

Toxicological or dietary exposure monographs on most of the substances that were considered will be published in WHO Food Additives Series No. 62. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs 7.

More information on the work of JECFA is available at:

http://www.fao.org/ag/agn/agns/jecfa_index_en.asp

and

<http://www.who.int/ipcs/food/jecfa/en/index.html>

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Toxicological recommendations and information on specifications

1. Food additives evaluated

Food additive	Specifications ^a	Acceptable daily intake (ADI) and other toxicological recommendations
Branching glycosyltransferase from <i>Rhodothermus obamensis</i> expressed in <i>Bacillus subtilis</i>	N	The Committee allocated an ADI “ not specified ” for branching glycosyltransferase from <i>Rhodothermus obamensis</i> expressed in <i>Bacillus subtilis</i> used in the specified applications and in accordance with Good Manufacturing Practice.
Cassia gum	N, T	The Committee allocated an ADI “ not specified ” for cassia gum that complies with the tentative specifications established at the current meeting, when used in the applications specified and in accordance with Good Manufacturing Practice. The Committee decided to make the specifications tentative pending submission of data on a suitable and validated method for determination of anthraquinones at a level of 0.5 mg/kg and below, by the end of 2010.
Cyclamic acid and its salts (dietary exposure assessment)		Of the four maximum use levels (250, 500, 750 and 1000 mg/kg) that the Committee considered at the request of the Codex Committee on Food Additives (CCFA) for cyclamates in beverages covered by General Standard for Food Additives (GSFA) Food Category 14.1.4, only the lowest level of 250 mg/kg was not likely to lead to dietary exposures exceeding the ADI for high consumers, including children. Moreover, it was noted that a maximum use level of 350 mg/kg also resulted in dietary exposures for high consumers, including children, that were less than the ADI.
Cyclotetraglucose and cyclotetraglucose syrup	R (cyclotetraglucose syrup)	The Committee removed the temporary designation and established an ADI “ not specified ” for cyclotetraglucose and cyclotetraglucose syrup. The specifications for cyclotetraglucose syrup were revised, and the tentative designation was removed.

Food additive	Specifications ^a	Acceptable daily intake (ADI) and other toxicological recommendations
Ferrous ammonium phosphate	N	<p>The newly available information on the toxicity of iron did not indicate a need to revise the provisional maximum tolerable daily intake (PMTDI) of 0.8 mg/kg body weight. Consideration of the toxicity of ammonium and phosphate did not indicate a need to revise the Committee's previous evaluations of these ions.</p> <p>The Committee concluded that ferrous ammonium phosphate is acceptable for use as a source of iron for dietary fortification, provided that the total intake of iron does not exceed the PMTDI.</p> <p>Products, including ferrous ammonium phosphate, that are intended to provide a source of additional iron should not be consumed by individuals with any type of iron storage disease, except under medical supervision.</p>
Glycerol ester of gum rosin (GEGR)	N, T	<p>The Committee decided to include GEGR in the ADI for glycerol esters of wood rosin (GEWR) of 0–25 mg/kg body weight, thereby establishing a group ADI of 0–25 mg/kg body weight for GEWR and GEGR.</p> <p>The specifications for GEGR were made tentative pending the submission of infrared spectra that correspond to the commercially available products, data on the resin acid composition obtained with updated chromatographic techniques, and additional information on methods that enables the identification of the individual glycerol esters of rosins and their differentiation. This information should be submitted by the end of 2010.</p>
Glycerol ester of tall oil rosin (GETOR)	N, T	<p>The Committee concluded in principle that the data from GEWR could be used in the evaluation of GETOR; however, the Committee did not have adequate information on the composition of GETOR, considering that the source material and production processes are different, which may result in different by-products.</p> <p>The Committee decided that it could not evaluate GETOR without additional information on its composition in order to clarify the extent and significance of any differences relative to other glycerol esters of rosins.</p> <p>The specifications for GETOR were made tentative pending the submission of infrared spectra that correspond to the commercially</p>

Food additive	Specifications ^a	Acceptable daily intake (ADI) and other toxicological recommendations
Lycopene from all sources		<p>available products, data on the resin acid composition obtained with updated chromatographic techniques, and additional information on methods that enables the identification of the individual glycerol esters of rosins and their differentiation. The Committee also requested information on the identity of the sulfur compounds in the commercial product. This information should be submitted by the end of 2010.</p> <p>The Committee decided to revise the group ADI established at the sixty-seventh meeting and replace it with a group ADI “not specified” for lycopene from all sources when used as food colour. Hence, the previous group ADI of 0–0.5 mg/kg for lycopene has been withdrawn.</p> <p>The group ADI “not specified” applies to synthetic lycopene, lycopene derived from the fungus <i>Blakeslea trispora</i> and lycopene extract from tomato that comply with the specifications, when used in accordance with Good Manufacturing Practice.</p>
Lycopene extract from tomato	N	<p>The Committee established a group ADI “not specified” for synthetic lycopene, lycopene derived from the fungus <i>Blakeslea trispora</i> and lycopene extract from tomato, when used as food colour, that comply with the specifications, and when used in accordance with Good Manufacturing Practice.</p>
Mineral oil (low and medium viscosity) class II and class III		<p>The Committee was informed that finalization of the requested studies has been delayed. The Committee decided to further extend the temporary group ADI, but noted that the temporary group ADI will be withdrawn at the end of 2011 if the data are not submitted by that time.</p>
Octenyl succinic acid (OSA) modified gum arabic	N	<p>The Committee decided to allocate a temporary ADI “not specified” for OSA modified gum arabic used in the applications specified and in accordance with Good Manufacturing Practice. The ADI is temporary pending submission of data by the end of 2011 showing hydrolysis of OSA modified gum arabic to confirm the validity of using gum arabic data in the evaluation of OSA modified gum arabic.</p>
Sodium hydrogen sulfate	R	<p>The Committee allocated an ADI “not specified” for sodium hydrogen sulfate, in line with the principles established for ionizable salts at its twenty-ninth meeting,</p>

Food additive	Specifications ^a	Acceptable daily intake (ADI) and other toxicological recommendations
Sucrose oligoesters (SOE) type I and type II	N	<p>when used in the applications specified and in accordance with Good Manufacturing Practice.</p> <p>Specifications were revised to include a new technological use.</p> <p>The Committee considered it appropriate to include SOE type I and type II in a group ADI of 0–30 mg/kg body weight for sucrose esters of fatty acids, sucroglycerides and SOE type I and type II. The Committee emphasized that this evaluation is valid only for the material as specified.</p>

^a N, new specifications prepared; R, existing specifications revised; T, tentative specifications.

^b ADI “not specified” is used to refer to a food substance of very low toxicity that, on the basis of the available data (chemical, biochemical, toxicological and other) and the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effects and from its acceptable background levels in food, does not, in the opinion of the Committee, represent a hazard to health. For that reason, and for the reasons stated in the individual evaluations, the establishment of an ADI expressed in numerical form is not deemed necessary. An additive meeting this criterion must be used within the bounds of Good Manufacturing Practice—i.e. it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal food of inferior quality or adulterated food, and it should not create a nutritional imbalance.

2. Food additives considered for specifications only

Food additive	Specifications ^a
Diacetyltartaric and fatty acid esters of glycerol	R
Ethyl lauroyl arginate	R
Glycerol ester of wood rosin	R, T
Nisin preparation	R
Nitrous oxide	R, T
Pectins	R
Starch sodium octenyl succinate	R
Tannic acid	R
Titanium dioxide	R
Triethyl citrate	R

^a R, existing specifications revised; T, tentative specifications.

Annex 1

**Seventy-first meeting of the
Joint FAO/WHO Expert Committee on Food Additives**
Geneva, 16–24 June 2009

Members

- Professor J. Bend, Department of Pathology, Siebens-Drake Medical Research Institute, Schulich School of Medicine & Dentistry, University of Western Ontario, London, Ontario, Canada (*Unable to participate*)
- Dr Y. Kawamura, Division of Food Additives, National Institute of Health Sciences, Tokyo, Japan
- Dr A.G.A.C. Knaap, Bilthoven, Netherlands
- Dr P.M. Kuznesof, Consultant, Silver Spring, MD, United States of America (USA) (*Unable to participate*)
- Dr J.C. Larsen, National Food Institute, Technical University of Denmark, Søborg, Denmark (*Joint Rapporteur*)
- Dr A. Mattia, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*Vice-Chairperson*)
- Mrs I. Meyland, National Food Institute, Technical University of Denmark, Søborg, Denmark (*Chairperson*)
- Dr Z. Olempska-Beer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA
- Dr J. Schlatter, Nutritional and Toxicological Risks Section, Federal Office of Public Health, Zurich, Switzerland
- Dr M. Veerabhadra Rao, Department of Chemistry, College of Science, United Arab Emirates University, Al Ain, United Arab Emirates
- Dr P. Verger, French National Institute for Agricultural Research (INRA) – AgroParisTech, Paris, France
- Professor R. Walker, School of Biomedical and Health Sciences, University of Surrey, Guildford, Surrey, United Kingdom
- Mrs H. Wallin, National Food Safety Authority (Evira), Helsinki, Finland (*Joint Rapporteur*)
- Dr B. Whitehouse, Consultant, Bowdon, Cheshire, United Kingdom

Secretariat

- Ms J. Baines, Food Standards Australia New Zealand, Canberra, ACT, Australia (*FAO Expert*)
- Dr A. Bruno, Joint FAO/WHO Food Standard Programme, Food and Agriculture Organization, Rome, Italy (*FAO Codex Secretariat*)
- Dr J. Chen, Chairman of the Codex Committee on Food Additives (CCFA), National Institute of Nutrition and Food Safety, Beijing, China (*WHO Temporary Adviser*)
- Dr M. Choi, Department of Food Safety, Zoonoses and Foodborne Diseases, World Health Organization, Geneva, Switzerland (*WHO Staff Member*)
- Dr R. P. Danam, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*WHO Temporary Adviser*)
- Dr M. DiNovi, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*WHO Temporary Adviser*)
- Dr Y. Fan, Department of Food Safety, Zoonoses and Foodborne Diseases, World Health Organization, Geneva, Switzerland (*WHO Staff Member*)
- Dr R. Harrison, Food Standards Agency, London, England (*WHO Temporary Adviser*)
- Dr S.M.F. Jeurissen, Centre for Substances and Integrated Risk Assessment, National Institute for Public Health and the Environment, Bilthoven, Netherlands (*WHO Temporary Adviser*)
- Dr H. Lee, National Institute of Toxicological Research, Korea Food and Drug Administration, Seoul, Republic of Korea (*WHO Temporary Adviser*)

- Professor S.M. Mahungu, Dairy, Food Science and Technology Department, Egerton University, Njoro, Kenya (*FAO Expert*)
- Dr U.W. Mueller, Food Standards Australia New Zealand, Canberra, ACT, Australia (*WHO Temporary Adviser*)
- Professor S. Rath, Department of Analytical Chemistry, Institute of Chemistry, State University of Campinas, Campinas, Sao Paulo, Brazil (*FAO Expert*)
- Ms M. Sheffer, Ottawa, Canada (*WHO Editor*)
- Professor I. Stankovic, Institute of Bromatology, Faculty of Pharmacy, University of Belgrade, Belgrade, Serbia (*FAO Expert*)
- Professor M.C. de Figueiredo Toledo, Faculty of Food Science, State University of Campinas, Campinas, Sao Paulo, Brazil (*FAO Expert*)
- Dr A. Tritscher, Department of Food Safety, Zoonoses and Foodborne Diseases, World Health Organization, Geneva, Switzerland (*WHO Joint Secretary*)
- Dr T. Umemura, Biological Safety Research Center, National Institute of Health Sciences, Tokyo, Japan (*WHO Temporary Adviser*)
- Dr A. Wennberg, Nutrition and Consumer Protection Division, Food and Agriculture Organization, Rome, Italy (*FAO Joint Secretary*)

Annex 2

Further information required and desired and recommendations

Further information required

Cassia gum

Information is required on a suitable and validated method for determination of anthraquinones in cassia gum at a level of 0.5 mg/kg and below. This information should be submitted by the end of 2010.

Glycerol ester of gum rosin (GEGR)

The Committee requested that it be provided with full reports of the two 90-day toxicity studies with GEGR in rats fed dietary concentrations of up to 1.0% to confirm the validity of the comparison of glycerol ester of wood rosin (GEWR) with GEGR.

The specifications were made tentative pending the submission of infrared spectra that correspond to the commercially available products, data on the resin acid composition obtained with updated chromatographic techniques, and additional information on methods that enables the identification of the individual glycerol esters of rosins and their differentiation. This information should be submitted by the end of 2010.

Glycerol ester of tall oil rosin (GETOR)

The Committee did not have adequate information on the composition of GETOR, as the source material and production processes are different, which may result in different by-products. Therefore, the Committee decided that it could not evaluate GETOR without additional information on its composition in order to clarify the extent and significance of any differences relative to other glycerol esters of rosins.

The specifications were made tentative pending the submission of infrared spectra that correspond to the commercially available products, data on the resin acid composition obtained with updated chromatographic techniques, and additional information on methods that enables the identification of the individual glycerol esters of rosins and their differentiation. The Committee also requested information on the identity of the sulfur compounds in the commercial products. This information should be submitted by the end of 2010.

Glycerol ester of wood rosin (GEWR)

The specifications were made tentative pending the submission of infrared spectra that correspond to the commercially available products, data on the resin acid composition obtained with updated chromatographic techniques, and additional information on methods that enables the identification of the individual glycerol esters of rosins and their differentiation. This information should be submitted by the end of 2010.

Mineral oil (low and medium viscosity) class II and class III

The Committee at its current meeting was informed that studies are under way but that technical problems had been encountered that will delay the finalization of the requested studies. The Committee received confidential information on the studies and nature of the problems and, based on this, decided to further extend the temporary group ADI. The

Committee noted that the temporary group ADI will be withdrawn at the end of 2011 if the data are not submitted by that time.

Nitrous oxide

The revised specifications were made tentative, as information on a capillary gas chromatographic assay method was required. This information should be submitted by the end of 2010.

Octenyl succinic acid (OSA) modified gum arabic

The ADI is temporary pending submission of data by the end of 2011 showing hydrolysis of OSA modified gum arabic to confirm the validity of using gum arabic data in the evaluation of OSA modified gum arabic.

Recommendation

To better assess chronic dietary exposure, the Committee recommends the use of food consumption data collected over a period of more than 1 day with an averaging of the amounts of food consumed per day. Moreover, the Committee recommends that food consumption data collected over a few days be adjusted by using food frequency questionnaires on a comparable population where these data are available.

Annex 3**General considerations**

An edited version of this section will appear in the report of the seventy-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). It is reproduced here so that the information can be disseminated quickly. This draft will be subject to editing.

Guidelines for the safety evaluation of enzymes produced by genetically modified microorganisms (GMMs)

At its sixty-fifth meeting, the Committee concluded that guidelines need to be developed on the safety evaluation of enzymes produced by GMMs. At the sixty-eighth meeting, the Committee noted the ongoing international initiatives to elaborate guidelines for the safety evaluation of enzymes (including those from GMMs) and microorganisms intended for food applications. At the present meeting, the Committee discussed the new regulation for enzymes enacted by the European Parliament and related guidance documents.

The Committee decided to update the General Specifications and Considerations for Enzymes Used in Food Processing to expand recommendations for microbiology and molecular biology information to be submitted in dossiers for enzymes from microorganisms (including those from GMMs) and to discuss toxicological and other safety studies for enzymes from all sources.

The Committee recommended that the JECFA Secretariat establish a working group to update the current guidance document on enzymes for discussion at a future meeting.