



Food and Agriculture
Organization of
the United Nations



World Health
Organization

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES
Seventy-seventh meeting
Rome, 4–13 June 2013

SUMMARY AND CONCLUSIONS

Issued 19 June 2013, Revised 20 November 2013

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Rome, Italy, from 4 to 13 June 2013. The purpose of the meeting was to evaluate certain food additives and contaminants.

Mrs I. Meyland, Denmark, served as Chairperson, and Dr D. Benford, Food Standards Agency, United Kingdom, served as Vice-Chairperson.

Mr S.J. Crossley, Food Safety, Food and Agriculture Organization of the United Nations, and Dr A. Tritscher, Department of Food Safety and Zoonoses, World Health Organization, served as Joint Secretaries.

The present meeting was the seventy-seventh 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 contaminants 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 or tolerable daily intakes 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 is listed in Annex 2. Items of a general nature that the Committee would like to disseminate quickly are included in Annex 3.

Toxicological and dietary exposure monographs on certain of the substances that were considered will be published in WHO Food Additives Series No. 68. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs 14.

More information on the work of JECFA is available at:

<http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/>

and

<http://www.who.int/foodsafety/chem/jecfa/en/index.html>

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Toxicological and dietary exposure information and information on specifications

Food additives considered for specifications only

Food additive	Specifications ^a
Aluminium silicate	R, T
Annatto extracts (solvent-extracted bixin)	M
Annatto extracts (solvent-extracted norbixin)	M
Benzoe tonkinensis	M, T
Calcium aluminium silicate	R, T
Calcium silicate	R, T
Food additives containing phosphates	R ^b
Mineral oil (medium viscosity)	R
Modified starches	R ^c
Paprika extract	R ^d
Phytase from <i>Aspergillus niger</i> expressed in <i>Aspergillus niger</i>	R
Potassium aluminium silicate	R ^d
Potassium aluminium silicate–based pearlescent pigments, Type I	N ^e
Potassium aluminium silicate–based pearlescent pigments, Type II	N ^e
Potassium aluminium silicate–based pearlescent pigments, Type III	N ^e
Silicon dioxide, amorphous	R, T
Sodium aluminosilicate	R, T

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

^b The inductively coupled plasma – atomic emission spectrophotometric (ICP-AES) method for the assay of phosphate additives was added to the *Combined Compendium of Food Additive Specifications*.

^c The method for determination of percentage of octenyl succinate groups in starch sodium octenyl succinate was revised.

^d The tentative status of the specifications was removed.

^e The existing combined specifications for potassium aluminium silicate–based pearlescent pigments were split into three separate specifications (Type I: coated with titanium oxide only, Type II: coated with iron oxide only and Type III: coated with both titanium dioxide and iron oxide). The tentative status of the specifications was removed.

Food additives evaluated toxicologically, assessed for dietary exposure and considered for specifications

Food additive	Specifications ^a	Acceptable daily intakes, other toxicological recommendations and dietary exposure assessment
Advantame	N, T	<p>The Committee established an acceptable daily intake (ADI) of 0–5 mg/kg body weight (bw) for advantame on the basis of a no-observed-adverse-effect level (NOAEL) of 500 mg/kg bw per day for maternal toxicity in a developmental toxicity study in rabbits and application of a 100-fold safety factor to account for interspecies and intraspecies variability.</p> <p>The Committee agreed that the ADI also applies to those individuals with phenylketonuria, as the formation of phenylalanine from the normal use of advantame would not be significant in relation to this condition.</p> <p>Using the proposed maximum use levels and conservative assumptions, the maximum mean dietary exposure to advantame would be 1.45 mg/kg bw per day (29% of the upper bound of the ADI), and the maximum high-percentile dietary exposure would be 2.16 mg/kg bw per day (43% of the upper bound of the ADI).</p>
Glucoamylase from <i>Trichoderma reesei</i> expressed in <i>Trichoderma reesei</i>	N	Based on its low toxicity and because it is reasonably anticipated that dietary exposure would be very low, the Committee established an ADI “not specified”^b for the glucoamylase enzyme preparation from <i>T. reesei</i> expressed in <i>T. reesei</i> used in the applications specified and in accordance with good manufacturing practice.
Glycerol ester of gum rosin (GEGR)	M, T	As the requested two unpublished 90-day oral toxicity studies on GEGR in rats and complete information on the composition of GEGR were not submitted, the Committee withdrew the temporary group ADI of 0–12.5 mg/kg bw for GEGR and glycerol ester of wood rosin (GEWR) (see below).
Glycerol ester of tall oil rosin (GETOR)	W	No data on GETOR were submitted, and the Secretariat was informed that this compound is no longer supported by the previous data sponsor. Therefore, the Committee did not evaluate GETOR.
Glycerol ester of wood rosin (GEWR)	R ^c	As the requested data on GEGR were not submitted, the Committee withdrew the temporary group ADI of 0–12.5 mg/kg bw for GEGR and GEWR and re-established the ADI of 0–25 mg/kg bw for GEWR.
Nisin	R	<p>The Committee established an ADI for nisin of 0–2 mg/kg bw on the basis of a NOAEL of 224.7 mg of nisin per kilogram body weight per day from a 13-week study in rats and application of a safety factor of 100 to account for interspecies and intraspecies variability. The Committee did not consider it necessary to use an additional safety factor to account for the short duration of the study because no compound-related effects were observed at any dose in any of the toxicity studies, including the reproductive toxicity study, and because ingested nisin is degraded in the upper part of the intestinal tract, such that systemic exposure to nisin is not likely to occur.</p> <p>The highest estimated dietary exposure of 0.07 mg of nisin per</p>

Food additive	Specifications ^a	Acceptable daily intakes, other toxicological recommendations and dietary exposure assessment
		<p>kilogram body weight per day determined at the current meeting did not exceed the upper bound of the ADI.</p> <p>The Committee withdrew the previous ADI of 0–33 000 units of nisin per kilogram body weight established at the twelfth meeting.</p>
Octenyl succinic acid (OSA) modified gum arabic	R, T	The Committee decided to retain the temporary ADI “not specified”^b pending submission of additional data on the stability of OSA modified gum arabic in food by the end of 2013, which may help to explain contradictory hydrolysis data.

^a M, existing specifications maintained; N, new specifications; R, existing specifications revised; T, tentative specifications; W, existing specifications withdrawn.

^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 exposure to 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.

^c The tentative status of the specifications was removed.

Contaminants

Cadmium: Assessment of exposure from cocoa and cocoa products

The Codex Committee on Contaminants in Foods, at its Sixth Session, requested that the Committee conduct an assessment of dietary exposure to cadmium from cocoa and cocoa products.

The estimates of mean population dietary exposure to cadmium from products containing cocoa and its derivatives for the 17 new Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme (GEMS/Food) Cluster Diets (see Annex 3) ranged from 0.005 to 0.39 µg/kg bw per month, which equated to 0.02–1.6% of the provisional tolerable monthly intake (PTMI) of 25 µg/kg bw. Similar mean population cadmium dietary exposures for individual cocoa products were estimated from national data, ranging from 0.001 to 0.46 µg/kg bw per month (0.004–1.8% of the PTMI).

The potential dietary exposures to cadmium for high consumers of products containing cocoa and its derivatives in addition to cadmium derived from other foods were estimated to be 30–69% of the PTMI for adults and 96% of the PTMI for children 0.5–12 years of age. **The Committee noted that this total cadmium dietary exposure for high consumers of cocoa and cocoa products was likely to be overestimated and did not consider it to be of concern.**

Detailed information on cadmium occurrence data and national food consumption data used in the evaluation will be available on the JECFA web site.

Annex 1

**Seventy-seventh meeting of the
Joint FAO/WHO Expert Committee on Food Additives**
Rome, 4–13 June 2013

Members

- Dr D. Benford, Food Standards Agency, London, United Kingdom (*Vice-Chairperson*)
- Dr M. DiNovi, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, United States of America (USA)
- Dr D. Folmer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA
- Dr Y. Kawamura, Division of Food Additives, National Institute of Health Sciences, Tokyo, Japan
- Dr Madduri Veerabhadra Rao, Department of the President's Affairs, Al Ain, United Arab Emirates
- Mrs I. Meyland, Birkerød, Denmark (*Chairperson*)
- Dr U. Mueller, Food Standards Australia New Zealand, Barton, ACT, Australia (*Joint Rapporteur*)
- Dr J. Schlatter, Zurich, Switzerland
- Dr P. Sinhaseni, Community Risk Analysis Research and Development Center, Bangkok, Thailand
- Mrs H. Wallin, Helsinki, Finland (*Joint Rapporteur*)

Secretariat

- Ms J. Baines, Food Standards Australia New Zealand, Canberra, ACT, Australia (*FAO Expert*)
- Ms G. Brisco, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations, Rome, Italy (*Codex Secretariat*)
- Ms A. Bruno, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations, Rome, Italy (*Codex Secretariat*)
- Dr S. Cahill, Agriculture and Consumer Protection Department, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Secretariat*)
- Dr R. Cantrill, AOCS, Urbana, IL, USA (*FAO Expert*)
- Dr V. Carolissen, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations, Rome, Italy (*Codex Secretariat*)
- Dr S. Choudhuri, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*WHO Expert*)
- Mr S.J. Crossley, Food Safety, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Joint Secretary*)
- Dr V. Fattori, Agriculture and Consumer Protection Department, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Secretariat*)
- Mr M. Feeley, Food Directorate, Health Canada, Ottawa, Canada (*WHO Expert*)
- Dr E. Furukawa, Department of Food Safety and Zoonoses, World Health Organization, Geneva, Switzerland (*WHO Secretariat*)
- Dr Y. Ito, Division of Food Additives, National Institute of Health Sciences, Tokyo, Japan (*FAO Expert*)
- Dr F. Kayama, School of Medicine, Jichi Medical University, Tochigi, Japan (*WHO Expert*)

Mr J. Kim, Department of Food Safety and Zoonoses, World Health Organization, Geneva, Switzerland (*WHO Secretariat*)

Professor S. Rath, Department of Analytical Chemistry, University of Campinas, Campinas, São Paulo, Brazil (*FAO Expert*)

Ms M. Sheffer, Ottawa, Canada (*WHO Editor*)

Dr J.R. Srinivasan, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*FAO Expert*)

Professor I. Stankovic, Faculty of Pharmacy, University of Belgrade, Belgrade, Serbia (*FAO Expert*)

Dr A. Tritscher, Department of Food Safety and Zoonoses, World Health Organization, Geneva, Switzerland (*WHO Joint Secretary*)

Dr T. Umemura, Biological Safety Research Center, National Institute of Health Sciences, Tokyo, Japan (*WHO Expert*)

Dr G. Wolterink, National Institute for Public Health and the Environment (RIVM), Bilthoven, the Netherlands (*WHO Expert*)

Dr H.J. Yoon, Hazardous Substances Analysis Division, Ministry of Food and Drug Safety, Seoul, Republic of Korea (*WHO Expert*)

Annex 2

Further information required or desired

Advantame

The specifications are tentative, pending the submission of information, by the end of 2015, on:

- the suitability of the headspace gas chromatographic method (using appropriate dissolution solvent) for determination of residual solvents, published in Volume 4 of the *Combined Compendium of Food Additive Specifications*, and data, in a minimum of five batches, using the method;
- an alternative or improved high-performance liquid chromatographic method for the assay of advantame and advantame acid using a standard curve;
- additional data and analytical methods for the determination of palladium and platinum;
- information on the purity and availability of the commercial reference standards used in the assay of advantame and advantame acid.

Annatto extracts (solvent-extracted bixin and solvent-extracted norbixin)

The Committee recommended that manufacturers supply residual solvent data from at least five batches of each of the solvent-extracted bixin and norbixin products to support the possible revision of the provision for residual solvents. To evaluate the suitability of the method for the determination of residual solvents in annatto extracts dissolved in dimethyl formamide, the Committee also recommended that manufacturers provide results from the analysis of samples of solvent-extracted bixin and norbixin products using this method as well as the general method for the determination of residual solvents published in Volume 4 of the *Combined Compendium of Food Additive Specifications*.

Benzoe tonkinensis

The tentative specifications will be withdrawn if the complete data on the composition of the ethanolic extract and microbiological contaminants are not received by the end of 2013.

Food additives containing aluminium and/or silicon

Specifications were made tentative pending the submission of information on composition; methods of manufacture; data on loss on drying and loss on ignition; impurities (lead, cadmium, arsenic and mercury) soluble in hydrochloric acid (0.5 mol/l); and suitability of the proposed ICP-AES method for assay, as well as data on the assay. Details on information required are included in the respective tentative specifications monographs. The tentative specifications will be withdrawn unless the requested information is received by the end of 2014.

Glycerol ester of gum rosin (GEGR)

The specifications were maintained as tentative pending the submission of additional information by the end of 2014. Additional data are requested to characterize GEGR in commerce in relation to the composition of 1) the refined gum rosin currently used as the source rosin with regard to the levels (%) of resin acids and neutrals, 2) the glycerol ester of gum rosin with regard to the levels (%) of a) glycerol esters, b) free resin acids and c) neutrals and 3) the total glycerol esters of resin acids with regard to the levels (%) of a) glycerol monoesters and b) the sum of glycerol di- and tri- esters (assay). Validated methods for the determination of the substances considered in the specifications are also required.

Octenyl succinic acid (OSA) modified gum arabic

The Committee noted that ongoing studies on the stability of OSA modified gum arabic in food may provide further information on its chemical state in food and aqueous solutions, which could help to explain the contradictory results of the hydrolysis study submitted to the Committee at the present meeting. The Committee decided to retain the temporary ADI “not specified” pending submission of additional data on the stability of OSA modified gum arabic in food by the end of 2013.

The Committee noted that the purity test of degree of esterification in the current specifications should be replaced by the degree of substitution and requested information for an analytical method to measure the degree of substitution and results of the analysis of at least five commercially available batches. The specifications were made tentative pending submission of these data by the end of 2013.

Annex 3

General considerations

This section contains brief summaries of information that will appear (in a longer and edited version) in the report of the seventy-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The information is included here so that it can be disseminated quickly.

Analytical methods for food additives

With respect to analytical methods for food additives, the Committee recommended that:

- appropriately validated methods be used;
- in relevant cases, the detailed analytical method be provided, together with validation data, in response to specific JECFA calls for data;
- the issue of the suitability of dissolution solvents for the determination of residual solvents in food additives be investigated at a future meeting;
- the suitability of an analytical method for the determination of carbon number at 5% distillation point using a wide-bore gas chromatographic column for use in the analysis of similar substances be evaluated at a future meeting;
- the method for the determination of cyclic phosphates be reviewed at a future meeting.

GEMS/Food consumption data

GEMS/Food diets report per capita amounts of food (grams per person per day) available for consumption, derived from FAO Food Balance Sheet data, to give the best coverage for all countries in the world, as dietary information at the individual level from national nutrition surveys is not available for many countries. Thirteen Cluster Diets were first developed in 1997 by grouping together countries that had geographical proximity as well as similar per capita data for 20 key foods, and these diets were revised in 2006 using updated FAO Food Balance Sheet data.

In 2012, a more sophisticated statistical approach was taken, involving an expanded set of FAO Food Balance Sheet data for 415 primary or semi-processed food products for 179 countries for the period from 2002 to 2007, to develop 17 new Cluster Diets, which replace the 13 Cluster Diets previously used.

In addition to Cluster Diets, FAO and WHO have recently developed a database that collates food consumption data derived from individual records for 26 countries for use in chronic and acute dietary exposure assessments.

The Committee welcomed the update of the WHO GEMS/Food Cluster Diets and the establishment of the food consumption database based on individual records from national surveys. The Committee applied the new Cluster Diets to evaluations at this meeting, where relevant. The Committee noted that both the Cluster Diets and the available individual food consumption data for individual countries should be considered in international food chemical dietary exposure assessments, with expert judgement required to determine their appropriate use.

FOSCOLLAB

The WHO Secretariat presented to the Committee a global platform for food safety data and information called FOSCOLLAB (Food Safety Collaboration), which was recently launched on the WHO web site¹. FOSCOLLAB integrates data and information from various existing WHO databases, such as JECFA evaluations, GEMS/Food contaminant occurrence data (including level of detection and average concentration by commodity), GEMS/Food consumption data and WHO Collaborating Centres, as well as the Codex *General Standard for Contaminants and Toxins in Food and Feed*.

The WHO Secretariat invited the meeting participants to test FOSCOLLAB and provide comments for further improvements.

¹ <http://www.who.int/foodsafety/foscollab/en/index.html>