



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



**World Health  
Organization**

**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES  
Seventy-fourth meeting  
Rome, 14–23 June 2011**

**SUMMARY AND CONCLUSIONS**

*Issued 4 July 2011*

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Rome, Italy, from 14 to 23 June 2011. The purpose of the meeting was to evaluate certain food additives and contaminants.

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 and Zoonoses, World Health Organization, served as Joint Secretaries.

The present meeting was the seventy-fourth in a series of similar meetings. The tasks before the Committee were (a) to elaborate principles governing the evaluation of food additives and contaminants, (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 and future work for the Committee are listed in Annexes 2 and 3. Items of a general nature that the Committee would like to disseminate quickly are included in Annex 4.

Toxicological and dietary exposure monographs on many of the substances that were considered will be published in WHO Food Additives Series No. 65. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs 11.

More information on the work of JECFA is available at:

[http://www.fao.org/ag/agn/agns/jecfa\\_index\\_en.asp](http://www.fao.org/ag/agn/agns/jecfa_index_en.asp)

and

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

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## Tolerable or acceptable daily intakes, other toxicological information and information on specifications

### *Food additives evaluated toxicologically and assessed for dietary exposure*

Food additive	Specifications <sup>a</sup>	Acceptable or tolerable daily intakes and other toxicological recommendations
Aluminium-containing food additives (including new food additives potassium aluminium silicate and potassium aluminium silicate-based pearlescent pigments)	N, T <sup>b</sup>	<p><b>The Committee established a provisional tolerable weekly intake (PTWI) of 2 mg/kg body weight</b> based on a no-observed-adverse-effect level (NOAEL) of 30 mg/kg body weight per day and application of a safety factor of 100. The PTWI applies to all aluminium compounds in food, including food additives. <b>The previous PTWI of 1 mg/kg body weight was withdrawn.</b> For adults, the estimates of mean dietary exposure to aluminium-containing food additives from consumption of cereals and cereal-based products are up to the PTWI. Estimates of dietary exposure of children to aluminium-containing food additives, including high dietary exposures (e.g. 90th or 95th percentile), can exceed the PTWI by up to 2-fold. For potassium aluminium silicate-based pearlescent pigments at the maximum proposed use levels and using conservative estimates, anticipated dietary exposure at the highest range of estimates is 200 times higher than the PTWI.</p> <p>The Committee emphasized that whereas substances that have long half-lives and accumulate in the body are not generally considered suitable for use as food additives, consumption of aluminium-containing food additives would not be a health concern, provided that total dietary exposure to aluminium is below the PTWI. The Committee recommended that provisions for food additives containing aluminium included in the Codex General Standard for Food Additives should be compatible with the revised PTWI for aluminium compounds of 2 mg/kg body weight as aluminium from all sources.</p>
Benzoe tonkinensis	N, T	<p><b>The Committee concluded that the available data were inadequate to establish an acceptable daily intake (ADI)</b> because of the variability in composition of Benzoe tonkinensis and the inadequate characterization of the material tested. The margin of exposure between the conservative dietary exposure estimate of 0.2 mg/kg body weight per day and the NOAEL of 500 mg/kg body weight per day identified in a 90-day oral toxicity study in rats is 2500. Given this margin of exposure as well as the nature of the hepatic effects observed at doses above the NOAEL and the negative genotoxicity results, <b>the Committee concluded that Benzoe tonkinensis would not pose a health concern at current estimated dietary exposures, provided that it complies with the tentative specifications prepared at the current meeting, when used as a flavouring agent and in</b></p>

Food additive	Specifications <sup>a</sup>	Acceptable or tolerable daily intakes and other toxicological recommendations
Glycerol ester of gum rosin (GEGR)	R, T	<p><b>accordance with good manufacturing practice.</b></p> <p>The Committee also noted that exposure to benzoic acid and benzyl benzoate from the use of Benzoe tonkinensis is well below the upper limit of the group ADI (0–5 mg/kg body weight) for benzyl derivatives, and exposure to vanillin is also well below the upper limit of its ADI (0–10 mg/kg body weight). The Committee further noted that benzoic acid, one of the major components of Benzoe tonkinensis, is used as a preservative, but that Benzoe tonkinensis has not been assessed for this use.</p> <p><b>The Committee withdrew the group ADI for GEGR and GEWR and established a temporary group ADI for GEGR and GEWR of 0–12.5 mg/kg body weight,</b> pending the submission of the full reports of the 90-day toxicity studies on GEGR as well as additional compositional information on the GEWR from <i>Pinus elliotii</i>. The Committee noted that the temporary group ADI will be withdrawn if the requested information is not submitted by the end of 2012.</p>
Glycerol ester of tall oil rosin (GETOR)	R, T	<p><b>The Committee was unable to complete the evaluation of GETOR</b> because additional data are required to characterize the GETOR in commerce. Validated methods for the determination of the substances considered in the specifications are also required. The above information should be submitted by the end of 2012.</p>
Glycerol ester of wood rosin (GEWR)	R, T	<p><b>The Committee withdrew the group ADI for GEGR and GEWR and established a temporary group ADI for GEGR and GEWR of 0–12.5 mg/kg body weight,</b> applying an additional safety factor of 2, because new information raises questions about the identity and composition of the product in commerce.</p> <p>Additional compositional information on the GEWR from <i>Pinus elliotii</i> to assess similarity with the GEWR from <i>Pinus palustris</i> is required. The Committee noted that the temporary group ADI will be withdrawn if the requested information is not submitted by the end of 2012.</p>
Octenyl succinic acid (OSA) modified gum arabic	R	<p><b>The Committee deferred further evaluation of OSA modified gum arabic</b> pending the submission of data on its stability in food and on the extent to which it is hydrolysed in the gastrointestinal tract, to be provided by the end of 2013. <b>The existing temporary ADI “not specified”<sup>c</sup> was retained.</b></p>
Polydimethyl siloxane	M	<p><b>The Committee withdrew the temporary ADI of 0–0.8 mg/kg body weight per day and re-established the ADI of 0–1.5 mg/kg body weight,</b> originally established at the eighteenth meeting.</p>
Ponceau 4R	R	<p><b>The Committee concluded that new data do not indicate a need to revise the existing ADI of 0–4 mg/kg body weight</b> and that dietary exposure to</p>

Food additive	Specifications <sup>a</sup>	Acceptable or tolerable daily intakes and other toxicological recommendations
		Ponceau 4R does not present a health concern.
Pullulan	R	Dietary exposure to pullulan as a dietary fibre could reach 1g/kg body weight per day for children (2–5 years old) and 0.4 g/kg body weight per day for the general population (2 years of age and older). These estimates are 8 and 20 times lower, respectively, than the no-observed-effect level (NOEL) observed in the 90-day rat study evaluated previously. Gastrointestinal effects observed in humans should be taken into account when considering appropriate use levels. The Committee stressed that it assessed the safety of use and not the efficacy of pullulan used as a dietary fibre. The Committee maintained the previously established ADI “not specified” <sup>c</sup> for the previously evaluated food additive uses.
Pullulanase from <i>Bacillus deramificans</i> expressed in <i>Bacillus licheniformis</i>	N	<b>The Committee established an ADI “not specified”<sup>c</sup> for pullulanase from <i>B. deramificans</i> expressed in <i>B. licheniformis</i> when used in the applications specified and in accordance with good manufacturing practice.</b>
Quinoline Yellow	R, T	<b>The Committee established a temporary ADI of 0–5 mg/kg body weight</b> , incorporating an additional 2-fold safety factor, pending submission of requested toxicological studies by the end of 2013. <b>The previously established ADI of 0–10 mg/kg body weight was withdrawn.</b> The conservative exposure estimates were within the range of the temporary ADI. Additional information on the composition of the product in commerce is required, in particular relating to the identity and purity of the unmethylated form of Quinoline Yellow.
Sunset Yellow FCF	M	<b>The Committee established an ADI of 0–4 mg/kg body weight and withdrew the previous ADI of 0–2.5 mg/kg body weight.</b> The Committee concluded that dietary exposure to Sunset Yellow FCF does not present a health concern.

<sup>a</sup> M, existing specifications maintained; N, new specifications prepared; R, existing specifications revised; T, tentative specifications.

<sup>b</sup> For potassium aluminium silicate and pearlescent pigments containing potassium aluminium silicate.

<sup>c</sup> 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.

**Food additives considered for specifications only**

Food additive	Specifications <sup>a</sup>
β-Apo-8'-carotenal	R
β-Apo-8'-carotenoic acid ethyl ester	R
β-Carotene, synthetic	R
Hydroxypropyl methyl cellulose	R <sup>b</sup>
Magnesium silicate, synthetic	R
Modified starches	R
Nitrous oxide	R
Sodium carboxymethyl cellulose	R
Sucrose monoesters of lauric, palmitic or stearic acid	R

<sup>a</sup> R, existing specifications revised; T, tentative specifications.

<sup>b</sup> The Committee concluded that levels of propylene chlorohydrins up to the new limit of not more than 1 mg/kg for the sum of both isomers in hydroxypropyl methyl cellulose were not of toxicological concern.

**Analytical methods for food additives in the Combined Compendium of Food Additive Specifications, Volume 4 (FAO JECFA Monographs 1, 2006)**

Food additive	Method <sup>a</sup>
Colouring matters content by spectrophotometry	R,T

<sup>a</sup> R, existing method revised; T, tentative method.

**Contaminants evaluated toxicologically***Cyanogenic glycosides*

The Third Session of the Codex Committee on Contaminants in Food (CCCF) in 2009 requested that JECFA reconsider the available data on cyanogenic glycosides, advise on the public health implications of cyanogenic glycosides and their derivatives in food and decide whether risk assessment is feasible and appropriate.

Reports of acute human poisoning associated with the consumption of foods containing cyanogenic glycosides were reviewed. The Committee therefore considered it appropriate to establish an acute reference dose (ARfD) for cyanogenic glycosides, expressed as cyanide equivalents. In addition, as there are a number of human diseases, specifically konzo, tropical ataxic neuropathy and iodine deficiency disorders, associated with the chronic consumption of underprocessed cassava as a staple food, it was recognized that the derivation of a chronic health-based guidance value would also be relevant.

Derivation of the ARfD

Following review of a developmental toxicity study with linamarin, the Committee considered this study as suitable for establishing an ARfD. Benchmark dose (BMD) modelling of the data from this study provided a lower limit on the benchmark dose for a 10% response (BMDL<sub>10</sub>) for linamarin of 85 mg/kg body weight for increased skeletal defects in developing hamster fetuses following acute exposure of maternal animals. While the study did not use dietary exposure, gavage dosing was considered relevant to establishing the ARfD.

Following application of a 100-fold uncertainty factor, the Committee established an ARfD for linamarin of 0.9 mg/kg body weight (equivalent to 0.09 mg/kg body weight as cyanide). This

value was considered, when compared on a cyanide molar basis, to also be applicable to other cyanogenic glycosides. Therefore, the Committee recommended conversion of the ARfD for linamarin to a cyanide-equivalent dose of 0.09 mg/kg body weight. This cyanide-equivalent ARfD applies only to foods containing cyanogenic glycosides as the main source of cyanide.

#### Derivation of the provisional maximum tolerable daily intake (PMTDI)

In a 13-week United States National Toxicology Program study not previously evaluated by the Committee, in which exposure to sodium cyanide was continuous via drinking-water, a variety of effects related to male reproductive organs were observed—namely, decreased cauda epididymis weights, decreased testis weights and decreased testicular spermatid concentration. Dose–response analysis of continuous data on absolute cauda epididymis weights generated the lowest BMDL for a one standard deviation response (BMDL<sub>1SD</sub>) of 1.9 mg/kg body weight per day. On the basis of this BMDL<sub>1SD</sub>, the Committee established a PMTDI of 0.02 mg/kg body weight by applying a 100-fold uncertainty factor. The Committee decided that it was not necessary to apply an additional uncertainty factor to account for the absence of a long-term study, considering the generally acute nature of cyanide toxicity and the sensitivity of the effect (i.e. the reduction of absolute cauda epididymis weight).

#### Comparison of estimated dietary exposures with health-based guidance values and the impact of maximum limits (MLs) on dietary exposure

Estimated dietary exposures to total available hydrocyanic acid (HCN) were converted to cyanide equivalents and compared with the health-based guidance values established by the Committee at this meeting.

From the national acute dietary exposure estimates available to the Committee for review, the ARfD of 0.09 mg/kg body weight as cyanide equivalents was exceeded 3-fold for cassava for adults (based on raw samples), less than 2-fold for apple juice for children, between 2- and 5-fold for bitter apricot kernels and up to 10-fold for ready-to-eat cassava chips/crisps, depending on the population group. If ready-to-eat cassava chips contained a level equivalent to the recently established ML in Australia and New Zealand of 10 mg/kg as HCN, there was only a marginal exceedance of the ARfD for children. These results are based on dietary exposure to total HCN, which represents the maximum possible exposure for foods containing cyanogenic glycosides.

Based on national estimates of chronic dietary exposure to total HCN, there is also the potential to exceed the PMTDI of 0.02 mg/kg body weight as cyanide for populations reliant on cassava as a staple food: between 1- and 3-fold for children and between 1- and 2-fold for adults. There is also a potential for those populations not reliant on cassava to exceed the PMTDI: between 1- and 5-fold for children and between 1- and 3-fold for adults. For Australia and New Zealand, ready-to-eat cassava chips were the major contributor to dietary exposure to HCN (84–93%). When the cassava chips contain a level equivalent to the ML of 10 mg/kg as HCN, all mean dietary exposures were below the PMTDI. High-percentile exposures for children were between 1- and 2-fold above the PMTDI. All chronic dietary exposure estimates based on exposures from flavouring agents did not exceed the PMTDI. These results are based on dietary exposure to total HCN, which is a worst-case scenario.

Application of the ML of 50 mg/kg as HCN for sweet cassava could result in dietary exposures that exceed the ARfD by less than 2-fold for the general population and up to 4-fold for children and exceed the PMTDI by between 2- and 10-fold, depending on the population group assessed. These estimates do not take into consideration any reduction in concentration of total HCN as a result of food preparation or processing. For the ML of 10 mg/kg as HCN for cassava flour, there are no estimates of dietary exposure available that exceed the ARfD or PMTDI. This is supported by the maximum amount of food that can be consumed based on existing Codex MLs before the health-based guidance values would be

exceeded, which is as low as 25 g/day for cassava for chronic exposure. More detailed estimates of cassava and cassava flour consumption and concentrations in food for cassava-eating communities would help in supporting the conclusion that dietary exposures to total HCN could exceed health-based guidance values.

The ML for sweet cassava is for the raw product. If the starting level of HCN in the raw sweet cassava were 50 mg/kg as HCN, the minimum effective processing would result in a concentration of 15 mg/kg as HCN, and the most effective processing would give a HCN concentration of 2 mg/kg.

**ARfD: 0.09 mg/kg body weight as cyanide (applies only to foods containing cyanogenic glycosides as the main source of cyanide)**

**PMTDI: 0.02 mg/kg body weight as cyanide**

### *Fumonisin*s

For the current evaluation of fumonisins, the Committee reviewed all relevant studies performed on fumonisins since 2001.

Exposure to fumonisins has been associated with a wide range of effects, which are often species and sex specific. Laboratory studies have identified the liver as the most sensitive organ in mice and the kidney as the most sensitive organ in rats.

Studies suitable for dose–response analysis have been conducted with rodents either employing purified fumonisin B<sub>1</sub> (FB<sub>1</sub>) or using *Fusarium verticillioides* culture material containing FB<sub>1</sub>. The latter studies typically use FB<sub>1</sub> as a marker for dietary exposure to the fumonisins and other metabolites of *Fusarium*. The studies employing purified FB<sub>1</sub> are generally better in experimental design for dose–response analysis. However, the Committee concluded that the studies with culture material were of sufficient quality to clearly indicate that other toxins produced by *F. verticillioides* either add to or potentiate the toxicity of FB<sub>1</sub>. Although naturally contaminated corn would probably be more representative of actual human dietary exposure than either purified FB<sub>1</sub> or culture material, no suitable studies were identified that used naturally contaminated corn as a test material. As the implications are somewhat different, the Committee evaluated studies with purified FB<sub>1</sub> and *F. verticillioides* culture material separately.

For pure FB<sub>1</sub>, the lowest identified BMDL<sub>10</sub> was 165 µg/kg body weight per day for megalocytic hepatocytes in male mice. Using a safety factor of 100 for intraspecies and interspecies variation, the Committee derived a PMTDI of 2 µg/kg body weight per day. As this was the same value as the previously established group PMTDI for FB<sub>1</sub>, FB<sub>2</sub> and FB<sub>3</sub>, alone or in combination, this group PMTDI was retained.

For culture material, the lowest identified BMDL<sub>10</sub> using FB<sub>1</sub> as a marker was 17 µg/kg body weight per day for renal toxicity in male rats. The Committee chose not to establish a health-based guidance value for culture material, because its composition was not well characterized and may not be representative of natural contamination.

The Committee concluded that, based on the national and international estimates, dietary exposure to FB<sub>1</sub> for the general population ranges from  $0.12 \times 10^{-3}$  to 7.6 µg/kg body weight per day at the mean, whereas the 95th percentile exposure was estimated to be up to 33.3 µg/kg body weight per day. Dietary exposure to total fumonisins for the general population would range, for a consumer with average consumption, from  $0.087 \times 10^{-3}$  to 10.6 µg/kg body weight per day, whereas for consumers with high consumption, exposure would be up to 44.8 µg/kg body weight per day. Maize is still the predominant source of exposure to FB<sub>1</sub> and total fumonisins.



Comparison of these estimates with the group PMTDI indicates that the group PMTDI is exceeded at the population level in some regions within some countries. The Committee concluded that adverse effects from fumonisin exposure may occur and that reduction of exposure to fumonisin and other toxins produced by *F. verticillioides* is highly desirable, particularly in areas of the world where maize is a major dietary staple food and where high contamination can occur.

As fumonisins do not carry over from feed to animal products in significant amounts, the occurrence of fumonisins in feed was considered not to be a human health concern.

The Committee concluded that implementation of the MLs proposed by CCCF could significantly reduce exposure (by more than 20%) to total fumonisins in six GEMS/Food consumption clusters (A, D, G, B, K, F). The main contribution to reduction was due to the proposed Codex ML for the category "Corn/maize grain, unprocessed". The Committee noted that implementation of the proposed MLs would result in rejection of 2–88% of "Corn/maize grain, unprocessed" and 4–57% of "Corn/maize flour/meal" across the clusters. The Committee also noted that the national estimates of exposure to fumonisins show that the exceedance of the PMTDI occurs only in limited regions presenting high maize consumption levels and highly contaminated maize.

The Committee concluded that no or little effect was noticed on the international exposure estimates resulting from the implementation of MLs higher than those proposed by CCCF.

**Group PMTDI for FB<sub>1</sub>, FB<sub>2</sub> and FB<sub>3</sub>, alone or in combination, of 2 µg/kg body weight was retained.**

**Annex 1**

**Seventy-fourth meeting of the  
Joint FAO/WHO Expert Committee on Food Additives**  
Rome, 14–23 June 2011

**Members**

- Dr M. Bolger, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA
- Dr M. DiNovi, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA
- Professor M.C. de Figueiredo Toledo, Faculdade de Engenharia de Alimentos, Universidade Estadual de Campinas, Campinas, São Paulo, Brazil
- Dr Y. Kawamura, Division of Food Additives, National Institute of Health Sciences, Tokyo, Japan
- 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
- Professor A. Renwick, Emeritus Professor, School of Medicine, University of Southampton, Ulverston, England (*Joint Rapporteur*)
- Dr J. Schlatter, Nutritional and Toxicological Risks Section, Federal Office of Public Health, Zurich, Switzerland
- Ms E. Vavasour, Ottawa, Ontario, Canada
- Dr M. Veerabhadra Rao, Department of the President's Affairs, Al Ain, United Arab Emirates
- Dr S. Resnik, Facultad de Ciencias Exactas y Naturales, Ciudad Universitaria, Buenos Aires, Argentina
- Professor R. Walker, Ash, Aldershot, Hantfordshire, England
- Mrs H. Wallin, Finnish Food Safety Authority (Evira), Helsinki, Finland (*Joint Rapporteur*)

**Secretariat**

- Dr A. Agudo, Catalan Institute of Oncology, L'Hospitalet de Llobregat, Spain (*WHO Temporary Adviser*)
- Mr D. Arcella, European Food Safety Authority, Parma, Italy (*FAO Expert*)
- Dr D. Benford, Food Standards Agency, London, England (*WHO Temporary Adviser*)
- Mrs G. Brisco, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Codex Secretariat*)
- Dr A. Bruno, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Codex Secretariat*)
- Ms A. Bulder, Centre for Substances and Integrated Risk Assessment, National Institute for Public Health and the Environment (RIVM), Bilthoven, the Netherlands (*WHO Temporary Adviser*)
- Mrs V. Carolissen-Mackay, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Codex Secretariat*)
- Dr C. Carrington, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*WHO Temporary Adviser*)
- Dr R. Danam, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*WHO Temporary Adviser*)
- Dr J.A. Edgar, CSIRO Food and Nutritional Sciences, North Ryde, Australia (*FAO Expert*)
- Mr M. Feeley, Food Directorate, Health Canada, Ottawa, Ontario, Canada (*WHO Temporary Adviser*)
- Dr D. Folmer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, USA (*FAO Expert*)
- Ms T. Hambridge, Food Standards Australia New Zealand, Canberra, Australia (*WHO Temporary Adviser*)

- Dr H. Kim, Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Codex Secretariat*)
- Dr K. Kpodo, Food Chemistry Division, CSIR-Food Research Institute, Accra, Ghana (*FAO Expert*)
- Dr J.-C. Leblanc, Food Risk Assessment Division, L'Agence nationale de la sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), Maisons-Alfort, France (*FAO Expert*)
- Professor S.M. Mahungu, Department of Dairy, Food Science and Technology, Egerton University, Egerton, Kenya (*FAO Expert*)
- Dr U.W. Mueller, Food Standards Australia New Zealand, Canberra, Australia (*WHO Temporary Adviser*)
- Professor S. Rath, Department of Analytical Chemistry, University of Campinas, Campinas, São Paulo, Brazil (*FAO Expert*)
- Dr R.T. Riley, Agricultural Research Service, United States Department of Agriculture, Athens, Georgia, USA (*WHO Temporary Adviser*)
- Ms M. Sheffer, Ottawa, Canada (*WHO Editor*)
- 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, Ministry of Health, Labour and Welfare, Tokyo, Japan (*WHO Temporary Adviser*)
- Dr A. Wennberg, Nutrition and Consumer Protection Division, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Joint Secretary*)
- Dr G. Wolterink, Centre for Substances and Integrated Risk Assessment, National Institute for Public Health and the Environment (RIVM), Bilthoven, the Netherlands (*WHO Temporary Adviser*)
- Dr F. Wu, Department of Environmental and Occupational Health, Graduate School of Public Health, University of Pittsburgh, Pittsburgh, PA, USA (*WHO Temporary Adviser*)

## Annex 2

### Further information required or desired

#### Aluminium-containing food additives

There is a need for convincing data to demonstrate that aluminium is not bioavailable from potassium aluminium silicate–based pearlescent pigments.

No data were available to identify the forms of aluminium present in soya-based formula and their bioavailability. Such studies were requested at the sixty-seventh meeting and are still required.

In the case of potassium aluminium silicate, information is required on preparation and purification methods, particle size distribution, methods of identification for silicate and aluminium, data on the levels of the inorganic impurities, the suitability of an inductively coupled plasma atomic emission spectrometry (ICP-AES) method for the determination of inorganic impurities, and the suitability of a proposed method based on alkali fusion followed by ICP-AES for the assay for potassium aluminium silicate based on the determination of aluminium.

In the case of potassium aluminium silicate–based pearlescent pigments, information is required on their manufacture, stability in food, particle size distribution, pH range, methods for the identification of iron, titanium and aluminium, data on the levels of the inorganic impurities, a filtration method appropriate for the small particle sizes associated with the pigments, and the suitability of a proposed method based on alkali fusion followed by ICP-AES for the assay for titanium, iron and aluminium.

The requested information should be made available by the end of 2012.

#### Benzoe tonkinensis

The Committee requested additional information regarding the complete composition of the ethanolic extract, data on microbiological contaminants and data on inorganic contaminants (lead, arsenic, antimony, chromium, mercury and cadmium). The Committee also requested an analytical method to distinguish between *Benzoe tonkinensis* and *Benzoe sumatranus*.

#### Cyanogenic glycosides

Further research is needed to more accurately quantify how nutritional factors ultimately contribute to the human diseases observed in populations whose diets consist mainly of improperly processed cassava, which involves high cyanide exposure.

There is a need for more extensive occurrence data for cyanogenic glycosides. These include data showing the ratio of cyanogenic glycosides to cyanohydrins to HCN in raw and processed versions of a range of foods containing cyanogenic glycosides. More occurrence data for foods other than cassava are needed, as are occurrence data for all foods from a broader range of countries around the world. Concentrations in foods as ready to consume would enable more accurate estimates of dietary exposure to be undertaken. Individual data points from analytical surveys would be of use to evaluate distributions of cyanogenic glycosides in foods and to define adequate sampling protocols. Distributions of occurrence data could then be used for probabilistic dietary exposure assessments.

More consumption data for cassava and cassava products from a broader range of countries would enable more detailed estimates of dietary exposure to be conducted or refined. More estimates of acute and chronic dietary exposures from a broader range of countries,

particularly African countries, would enable a better estimation of the global risk of dietary exposure to cyanogenic glycosides.

### **Fumonisin**

To be able to fully assess the toxic potential of culture material or naturally contaminated food, characterization and quantification of its mycotoxin content are necessary

To obtain a realistic representation of the effects of “real life” exposure and in order to compare the toxic potential of naturally contaminated feed with the findings in the studies used for the final evaluation, naturally contaminated feed should be tested in dose–response studies in animals.

As hidden and bound fumonisins have been detected in corn and corn products, further studies should be performed to elaborate more appropriate analytical methods in order to obtain additional occurrence data and information on the effects of processing.

As dietary exposure to fumonisins may occur with other mycotoxins, such as aflatoxins, well-designed laboratory and epidemiological studies are needed to assess interactions.

For the evaluation of co-occurrence, in food and feed, of fumonisins with other mycotoxins, concentrations of fumonisins and other mycotoxins must be provided at the level of the individual analytical sample.

Additional data on fumonisin distribution in corn food products should be collected in order to establish appropriate sampling procedures.

To validate urinary FB<sub>1</sub> as a potential candidate for a human biomarker of short-term exposure, large-scale human studies that indicate a well-characterized dose–response relationship between urinary FB<sub>1</sub> and dietary fumonisin exposures are needed. A biomarker for long-term exposure is also needed.

To investigate the association of fumonisin exposure with oesophageal cancer risk, child growth impairment and neural tube defects in humans, studies on fumonisin exposure and the incidence of these conditions in individuals (such as a cohort or case–control study) are needed. These studies should use a validated fumonisin exposure biomarker and control for confounders and for known risk factors.

### **Glycerol ester of gum rosin (GEGR)**

The requested full reports of the unpublished 90-day oral toxicity studies were not provided, and the validity of evaluating GEGR on the basis of toxicological data on glycerol ester of wood rosin (GEWR) still requires confirmation. To complete the evaluation of GEGR, the unpublished studies are required as well as additional data to characterize GEGR in commerce in relation to the composition of 1) the refined gum rosin currently used as the source rosin for the production of GEGR, 2) the glycerol ester of gum rosin, 3) the total glycerol esters of resin acids and 4) the neutrals. Validated methods for the determination of the substances considered in the specifications are also required. The information is required by the end of 2012.

### **Glycerol ester of tall oil rosin (GETOR)**

To complete the evaluation of GETOR, additional data are required to characterize the GETOR in commerce in relation to the composition of 1) the refined tall oil rosin used as the source rosin, 2) the glycerol ester of tall oil rosin, 3) the total glycerol esters of resin acids and 4) the neutrals. Validated methods for the determination of the substances considered in the specifications are also required. The above data are required by the end of 2012.

**Glycerol ester of wood rosin (GEWR)**

To complete the evaluation of GEWR, additional data are required to characterize the GEWR in commerce in relation to the composition of 1) the refined wood rosin used as the source rosin for the production of GEWR, 2) the glycerol ester of wood rosin, 3) the total glycerol esters of resin acids and 4) the neutrals. Validated methods for the determination of the substances considered in the specifications are also required.

**Method for colouring matter content by spectroscopy (Volume 4)**

Data on the wavelength of maximum absorbance, absorptivity and/or specific absorbance are requested for the following colours: Allura Red AC, Amaranth, Azorubine, Brilliant Black PN, Brilliant Blue FCF, Brown HT, Erythrosine, Fast Green FCF, Fast Red E, Green S, Indigotine, Patent Blue V, Ponceau 4R, Quinoline Yellow, Red 2G, Sunset Yellow FCF and Tartrazine. The data to be provided should also indicate the solvents used as well as any standardization for pH in order to allow for the establishment of consensus values for the wavelength of maximum absorbance, absorptivity and/or specific absorbance.

**Octenyl succinic acid (OSA) modified gum arabic**

The Committee requested that data resolving the concern about the stability of OSA modified gum arabic in food as well as data on the extent to which OSA modified gum arabic is hydrolysed in the gastrointestinal tract be provided by the end of 2013.

**Quinoline Yellow**

The Committee is aware of unpublished long-term studies in mice and rats with in utero exposure to Quinoline Yellow that had been completed by Biodynamics Laboratories in 1980–1981 but had not been submitted for evaluation and which might affect the ADI. These studies are requested by the end of 2013. The specifications are tentative pending submission of information regarding the principal components, maximum wavelengths for absorption, organic impurities, the level of zinc and a method of assay.

## **Annex 3**

### **Recommendations**

#### **Aluminium-containing food additives**

Provisions for food additives containing aluminium included in the Codex General Standard for Food Additives should be compatible with the revised PTWI for aluminium compounds of 2 mg/kg body weight as aluminium from all sources.

#### **Methods for analysis of propylene chlorohydrins**

The gas chromatography–mass spectrometric method introduced at the current meeting into the specifications monograph for hydroxypropyl methyl cellulose should be validated for use in the specifications monographs for hydroxypropyl cellulose, hydroxypropyl starch and hydroxypropyl distarch phosphate.

**Annex 4****General considerations**

*An edited version of this section will appear in the report of the seventy-fourth 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.*

**General comment about data submissions**

The Committee would like to emphasize that interested parties requesting an evaluation by the Committee need to be committed to providing all necessary data in a timely manner, as specified in the call for data. It is also important that they are prepared to respond to questions and to requests for clarifications or to provide additional data in a timely manner, both before and during the meeting. This refers to requests for safety assessments as well as to requests for the preparation or revision of specifications.

The Committee acknowledges that this requires a significant commitment and full cooperation on the part of those providing data. Such cooperation is, however, imperative to allow for complete evaluations without wasting the time and resources of the Committee.