



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



**World Health  
Organization**

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**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES  
Fifty-fifth meeting  
Geneva, 6-15 June 2000**

**SUMMARY AND CONCLUSIONS**

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held in Geneva, Switzerland, from 6 to 15 June 2000. The purpose of the meeting was to evaluate certain food additives and contaminants.

Professor R. Walker, Emeritus Professor of Food Science, School of Biological Sciences, University of Surrey, Guildford, Surrey, United Kingdom, served as Chairman and Dr P.M. Kuznesof, Leader, Chemistry and Exposure Assessment Team, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, DC, served as Vice-Chairman.

Dr J.L. Herrman, International Programme on Chemical Safety, World Health Organization, and Mrs M. de Lourdes Costarrica, Food Quality and Standards Service, Food and Nutrition Division, Food and Agriculture Organization of the United Nations, served as joint secretaries.

The present meeting was the fifty-fifth in a series of similar meetings. The tasks before the Committee were (a) to elaborate further principles for evaluating the safety of food additives and contaminants; (b) to assess certain food additives, flavouring agents, and contaminants; and (c) review and prepare specifications for selected food additives.

The report of the meeting will appear 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 recommendations. Information on specifications for the identity and purity of certain food additives examined by the Committee will also be included.

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Items of a general nature that contain information that the Committee would like to disseminate quickly are included in Annex 1. The participants are listed in Annex 2.

Toxicological monographs or monograph addenda on most of the substances that were considered will be published in WHO Food Additives Series No. 46.

Specifications for the identity and purity of the compounds listed in Table 1 marked as N; N,T; R; or R,T will be published in FAO Food and Nutrition Paper Series 52, Addendum 8. Specifications for substances marked as S and S,T have been published previously in that series. However, if these specifications have not been adopted as Codex Advisory Specifications, they will be re-published in FAO Food and Nutrition Paper Series No. 52, Addendum 8.

**NOTE**

*This document has been distributed prior to publication of the full report of the fifty-first meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to ensure the fast dissemination of information, in particular to the Codex Alimentarius Commission, to which JECFA is the scientific advisory body on matters relating to food additives and contaminants.*

*The FAO and WHO Joint Secretaries of JECFA request that further inquiries regarding the compounds evaluated at the meeting be made only **after** the official report has been published and distributed by WHO in the name of both sponsoring Organizations, FAO and WHO. Your cooperation is very much appreciated*

**Table 1**

**Acceptable Daily intakes (ADIs), other recommendations,  
and information on specifications**

**1. Food additives**

<b>Substance</b>	<b>Specifi- cations<sup>1</sup></b>	<b>Acceptable daily intake (ADI) and other toxicological recommendations</b>
<b>Flavouring agents</b> Furfural Paprika oleoresin	R S	0-0.5 mg/kg bw (group ADI) <sup>2</sup> Use of paprika oleoresin as a spice is acceptable <sup>3</sup>
<b>Food colours</b> Caramel colour II Cochineal extract and carmines	R <sup>4</sup> R	0-160 mg/kg bw May be allergenic <sup>5</sup>
<b>Sweetening agents</b> Aspartame-acesulfame salt  D-Tagatose	N  N	Aspartame and acesulfame moieties are covered by the ADIs established previously for aspartame (0-40 mg/kg bw) and acesulfame-K (0-15 mg/kg bw) No ADI allocated <sup>6</sup>
<b>Miscellaneous substances</b> Benzoyl peroxide Assessment of calcium intake from calcium salts of food additives Nitrous oxide Stearyl tartrate Trehalose	R - R R N	Additional uses could not be evaluated <sup>7</sup> Could not be assessed <sup>8</sup> Use as a packaging gas could not be assessed <sup>9</sup> Additional uses could not be evaluated <sup>7</sup> ADI "not specified" <sup>10</sup>

<sup>1</sup> N, new specification prepared; R, existing specification revised; S, specification exists, revision not considered or required; T, the existing new or revised specification is tentative and information is needed; W, existing specification withdrawn.

<sup>2</sup> Group ADI for furfural, furfuryl alcohol, furfuryl acetate, furfuryl propionate, furfuryl pentanoate, furfuryl octanoate, furfuryl 3-methylbutanoate, methyl 2-furoate, propyl 2-furoate, amyl 2-furoate, hexyl 2-furoate, and octyl 2-furoate.

<sup>3</sup> Paprika oleoresin was not evaluated at the present meeting. This opinion was based on the report of the fourteenth meeting of the Committee (WHO Technical Report Series, No. 462, 1971).

<sup>4</sup> Included in the specification for caramel colours.

<sup>5</sup> The Committee concluded that cochineal extract, carmines, and possibly carminic acid in foods and beverages may provoke allergic reactions in some individuals.

<sup>6</sup> An ADI could not be allocated because of concern about the potential of D-tagatose to induce glycogen deposition and hypertrophy in the liver and to increase the concentrations of uric acid in serum; see Table 2.

<sup>7</sup> No conclusions could be drawn about the acceptability of the uses proposed in the draft General Standard for Food Additives of the Codex Committee on Food Additives and Contaminants because information on toxicity and intake was not available.

<sup>8</sup> Data on levels of use and the food groups in which calcium salts of food additives are permitted would be required to assess calcium intake from calcium salts of food additives.

<sup>9</sup> No information on intake was available.

<sup>10</sup> ADI "not specified" is applied to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of the Committee, represent a hazard to health. For this reason, and for the reasons stated in the individual evaluation, the establishment of an ADI expressed in numerical form is not deemed necessary.

## 2. Flavouring agents evaluated using the Procedure for the Safety Evaluation of Flavouring Agents

### A. Cinnamyl alcohol and related flavouring agents

Flavouring Agent	No.	Specifi- cation <sup>1</sup>	Conclusions based on current intake
3-Phenyl-1-propanol	636	N	} No safety concern
3-Phenylpropyl formate	637	N	
3-Phenylpropyl acetate	638	N	
3-Phenylpropyl propionate	639	N	
3-Phenylpropyl isobutyrate	640	N	
3-Phenylpropyl isovalerate	641	N	} No safety concern
3-Phenylpropyl hexanoate	642	N,T	
Methyl 3-phenylpropionate	643	N	
Ethyl 3-phenylpropionate	644	N	
3-Phenylpropionaldehyde	645	N,T	
3-Phenylpropionic acid	646	N	} No safety concern
Cinnamyl alcohol	647	N	
Cinnamaldehyde ethylene glycol acetal	648	N,T	
Cinnamyl formate	649	N	
Cinnamyl acetate	650	N	
Cinnamyl propionate	651	N	} No safety concern
Cinnamyl butyrate	652	N,T	
Cinnamyl isobutyrate	653	N	
Cinnamyl isovalerate	654	N	
Cinnamyl benzoate	760	N,T	
Cinnamyl phenylacetate	655	N	} No safety concern
Cinnamaldehyde	656	N,T	
Cinnamic acid	657	N	
Methyl cinnamate	658	N	
Ethyl cinnamate	659	N	
Propyl cinnamate	660	N,T	} No safety concern
Isopropyl cinnamate	661	N	
Allyl cinnamate	019	S	
Butyl cinnamate	663	N,T	
Isobutyl cinnamate	664	N	
Isoamyl cinnamate	665	N	} No safety concern
Heptyl cinnamate	666	N,T	
Cyclohexyl cinnamate	667	N	
Linalyl cinnamate	668	N,T	
Terpinyl cinnamate	669	N,T	
Benzyl cinnamate	670	N	} No safety concern
Phenethyl cinnamate	671	N,T	
3-Phenylpropyl cinnamate	672	N,T	
Cinnamyl cinnamate	673	N,T	
<i>alpha</i> -Amylcinnamyl alcohol	674	N	
5-Phenylpentanol	675	N	} No safety concern
<i>alpha</i> -Amylcinnamyl formate	676	N,T	
<i>alpha</i> -Amylcinnamyl acetate	677	N,T	
<i>alpha</i> -Amylcinnamyl isovalerate	678	N,T	
3-Phenyl-4-pentenal	679	N	
3-( <i>p</i> -Isopropylphenyl) propionaldehyde	680	N	} No safety concern
<i>alpha</i> -Amylcinnamaldehyde dimethyl acetal	681	N,T	
<i>p</i> -Methylcinnamaldehyde	682	N	
<i>alpha</i> -Methylcinnamaldehyde	683	N	
<i>alpha</i> -Butylcinnamaldehyde	684	N	

Flavouring Agent	No.	Specification <sup>1</sup>	Conclusions based on current intake
alpha-Amylcinnamaldehyde	685	N	} No safety concern
alpha-Hexylcinnamaldehyde	686	N	
p-Methoxycinnamaldehyde	687	N	
o-Methoxycinnamaldehyde	688	N	
p-Methoxy-alpha-methyl-cinnamaldehyde	689	N	

### B. Furfuryl alcohol and related flavouring agents<sup>2</sup>

Flavouring agent	No.	Specification <sup>1</sup>	Conclusions based on current intake
Furfuryl alcohol <sup>3</sup>	451	R	} No safety concern
Furfuryl acetate <sup>3</sup>	739	N	
Furfuryl propionate <sup>3</sup>	740	N,T	
Furfuryl pentanoate <sup>3</sup>	741	N,T	
Furfuryl octanoate <sup>3</sup>	742	N,T	
Furfuryl 3-methylbutanoate <sup>3</sup>	743	N,T	} No safety concern
Furfural <sup>3</sup>	450	R	
5-Methylfurfural	745	N	
Methyl 2-furoate <sup>3</sup>	746	N	
Propyl 2-furoate <sup>3</sup>	747	N	
Amyl 2-furoate <sup>3</sup>	748	N,T	} No safety concern
Hexyl 2-furoate <sup>3</sup>	749	N,T	
Octyl 2-furoate <sup>3</sup>	750	N,T	
2-Benzofurancarboxaldehyde	751	N	
2-Phenyl-3-carbethoxyfuran	752	N,T	

### C. Phenol derivatives

Flavouring Agent	No.	Specification <sup>1</sup>	Conclusions based on current intake
Phenol	690	N	} No safety concern
o-Cresol	691	N	
m-Cresol	692	N	
p-Cresol	693	N	
p-Ethylphenol	694	N	
o-Propylphenol	695	N	} No safety concern
p-Propylphenol	696	N	
2-Isopropylphenol	697	N	
4-(1,1-Dimethylethyl) phenol	733	N	
Phenyl acetate	734	N	
o-Tolyl acetate	698	N,T	} No safety concern
p-Tolyl acetate	699	N	
o-Tolyl isobutyrate	700	N	
p-Tolyl isobutyrate	701	N	
p-Tolyl 3-methylbutyrate	702	N	
p-Tolyl octanoate	703	N	} No safety concern
p-Tolyl laurate	704	N,T	
p-Tolyl phenylacetate	705	N	
2,5-Xylenol	706	N	
2,6-Xylenol	707	N	
3,4-Xylenol	708	N	} No safety concern
2,3,6-Trimethylphenol	737	N,T	
Thymol	709	N	
Carvacrol	710	N	
2-Phenylphenol <sup>4</sup>	735	N,T	

Flavouring Agent	No.	Specification <sup>1</sup>	Conclusions based on current intake
p-Vinylphenol	711	N,T	} No safety concern
Resorcinol	712	N	
Guaiacol	713	N	
o-(Ethoxymethyl)phenol	714	N	
2-Methoxy-4-methylphenol	715	N	
4-Ethylguaiacol	716	N	} No safety concern
2-Methoxy-4-propylphenol	717	N	
Guaiacyl acetate	718	N	
Guaiacyl phenylacetate	719	N,T	
Hydroquinone monoethyl ether	720	N,T	
2,6-Dimethoxyphenol	721	N	} No safety concern
4-Methyl-2,6-dimethoxyphenol	722	N	
4-Ethyl-2,6-dimethoxyphenol	723	N,T	
4-Propyl-2,6-dimethoxyphenol	724	N,T	
2-Methoxy-4-vinylphenol	725	N	
4-Allyl-2,6-dimethoxyphenol	726	N,T	} No safety concern
2-Hydroxyacetophenone	727	N	
Phenyl salicylate	736	N	
4-(p-Hydroxyphenyl)-2-butanone	728	N	
Dihydroxyacetophenone	729	N,T	
Zingerone	730	N	} No safety concern
4-(p-Acetoxyphenyl)-2-butanone	731	N	
Vanillylidene acetone	732	N,T	

#### D. Pulegone and structurally related flavouring agents

Flavouring agent	No.	Specification <sup>1</sup>	Conclusions based on current intake
Isopulegone	754	N	} No safety concern
Isopulegol	755	N	
Isopulegyl acetate	756	N	
Pulegone	753	N	
p-Menth-1,4(8)-dien-3-one	757	N	
Menthofuran	758	N	

#### E. Flavouring agents considered for specifications only<sup>5</sup>

Flavouring agent	No.	Flavouring agent	No.
Allyl propionate	1	Acetaldehyde	80
Allyl phenylacetate	17	Acetic acid	81
Allyl cinnamate	19	Propionaldehyde	83
Allyl anthranilate	20	Propionic Acid	84
Allyl 2-furoate	21	Butyl alcohol	85
Ethyl undecanoate	36	Butyraldehyde	86
Ethyl hexadecanoate	39	Hexyl alcohol	91
Ethyl octadecanoate	40	Octanoic acid	99
Ethanol	41	Decanoic acid	105
Isoamyl hexanoate	46	Undecanoic acid	108
Isoamyl octanoate	47	Heptyl formate	121
Isoamyl nonanoate	48	Lauryl acetate	133
Citronellyl valerate	69	2-Ethylbutyl acetate	140
Geranyl isovalerate	75	cis-3 & trans-2-Hexenyl propionate	147

Flavouring agent	No.	Flavouring agent	No.
Heptyl butyrate	154	Isopropyl myristate	311
Octyl butyrate	155	<i>cis</i> -3-Hexenal	316
Decyl butyrate	156	3-Hexenoic acid	317
<i>cis</i> -3-Hexenyl hexanoate	165	<i>cis</i> -4-Hexenal	319
Isobutyl hexanoate	166	4-Heptenal	320
Propyl heptanoate	168	<i>cis</i> -6-Nonen-1-ol	324
Butyl heptanoate	169	5&6-Decenoic acid	327
Octyl heptanoate	171	Oleic Acid	333
Heptyl octanoate	176	Ethyl <i>cis</i> -4,7-octadienoate	339
Octyl octanoate	177	Methyl 3-nonenoate	340
Dodecyl isobutyrate	193	Ethyl <i>trans</i> -4-decenoate	341
2-Methylbutyl 3-methylbutanoate	204	Methyl 9-undecenoate	342
Ethyl 2-methylbutyrate	206	Ethyl 2-methyl-3,4-pentadienoate	353
n-Butyl 2-methylbutyrate	207	Methyl 3,7-dimethyl-6-octenoate	354
Hexyl 2-methylbutanoate	208	Linalyl isovalerate	363
Octyl 2-methylbutyrate	209	Linalyl octanoate	365
Isopropyl 2-methylbutyrate	210	Terpinyl isobutyrate	371
3-Hexenyl 2-methylbutanoate	211	p-Menth-3-en-1-ol	373
Methyl 2-methylpentanoate	213	p-Menthan-2-ol	376
Ethyl 2-methylpentanoate	214	Dihydrocarvone	377
Ethyl 3-methylpentanoate	215	d-Carvone	380.1
Methyl 4-methylvalerate	216	l-Carvone	380.2
<i>trans</i> -Anethole	217	Carvyl propionate	383
5-Ethyl-3-hydroxy-4-methyl-2(5H)-furanone	222	<i>beta</i> -Ionol	392
<i>gamma</i> -Heptalactone	225	Dihydro- <i>beta</i> -ionone	394
<i>gamma</i> -Octalactone	226	Methyl- <i>alpha</i> -ionone	398
4,4-Dibutyl- <i>gamma</i> -butyrolactone	227	Methyl- <i>delta</i> -ionone	400
<i>delta</i> -Octalactone	228	1,4-Dimethyl-4-acetyl-1-cyclohexene	402
<i>gamma</i> -Nonalactone	229	2-Acetoxy-3-butanone	406
<i>delta</i> -Decalactone	232	Butan-3-one-2-yl butanoate	407
$\omega$ -Pentadecalactone	239	4-Methyl-2,3-pentanedione	411
$\epsilon$ -Decalactone	241	2,3-Hexanedione	412
$\epsilon$ -Dodecalactone	242	5-Methyl-2,3-hexanedione	414
4,5-Dimethyl-3-hydroxy-2,5-dihydrofuran-2-one	243	Methylcyclopentenolone	418
5-Hydroxy-2,4-decadienoic acid <i>delta</i> lactone	245	3,4-Dimethyl-1,2-cyclopentanedione	420
5-Hydroxy-7-decenoic acid <i>delta</i> -lactone	247	3,5-Dimethyl-1,2-cyclopentanedione	421
5-Hydroxy-8-undecenoic acid <i>delta</i> -lactone	248	2-Hydroxy-3,5,5-trimethyl-2-cyclohexenone	426
Isobutyl alcohol	251	l-Menthyl lactate	433
Isobutyraldehyde	252	5-Hydroxy-2-dodecenoic acid <i>delta</i> -lactone	438
2-Ethylbutyraldehyde	256	4-Carvomethenol	439
4-Methyloctanoic acid	271	4-Thujanol	441
2-Tridecanone	298	d,1-Menthone 1,2-glycerol ketal	446
2-Pentadecanone	299	Furfuryl alcohol	451
3-Methyl-2-butanol	300	1,4-Dithiane	456
Isopropyl isovalerate	310	Allyl sulfide	458

Flavouring agent	No.	Flavouring agent	No.
4-(Methylthio)butanol	462	3-Mercapto-3-methyl-1-butanol	544
2-Methyl-4-propyl-1,3-oxathiane	464	2-Mercapto-3-butanol	546
3-(Methylthio)propionaldehyde	466	Ethyl 2-mercaptopropionate	552
3-(Methylthio)butanal	467	3-Mercapto-2-butanone	558
Ethyl 2-(methylthio)acetate	475	3-Mercapto-2-pentanone	560
3-(Methylthio)hexyl acetate	481	p-Mentha-8-thiol-3-one	561
S-Methyl thioacetate	482	Methyl propyl disulfide	565
Methyl thiobutyrate	484	Allyl disulfide	572
Methyl 2-methylthiobutyrate	486	3,5-Dimethyl-1,2,4-trithiolane	573
S-Methyl 3-methylbutanethioate	487	3-Methyl-1,2,4-trithiane	574
4-(Methylthio)-2-butanone	497	Dicyclohexyl disulfide	575
4,5-Dihydro-3(2H) thiophenone	498	Benzyl disulfide	579
2-Methyltetrahydrothiophen-3-one	499	Dimethyl trisulfide	582
4-(Methylthio)-4-methyl-2-pentanone	500	Methyl propyl trisulfide	584
o-(Methylthio)phenol	503	Dipropyl trisulfide	585
Methylsulfinylmethane	507	Diallyl trisulfide	587
Methyl mercaptan	508	Diallyl polysulfide	588
1-Propanethiol	509	2-Oxobutyric acid	589
2-Methyl-1-propanethiol	512	Ethyl 3-Hydroxybutyrate	594
3-Methylbutanethiol	513	Butyl acetoacetate	596
2-Pentanethiol	514	Isobutyl acetoacetate	597
Cyclopentanethiol	516	Isoamyl acetoacetate	598
1-Hexanethiol	518	Methyl 3-hydroxyhexanoate	600
2, 3, and 10-Mercaptopinane	520	Hydroxycitronellol	610
Allyl mercaptan	521	Hydroxycitronellal diethyl acetal	613
1-p-Menthene-8-thiol	523	Fumaric acid	618
Thiogeraniol	524	l-Malic acid	619
o-Toluenethiol	528	Diethyl malate	620
2-Ethyl(thiophenol)	529	Triethyl citrate	629
bis(Methylthio)methane	533	Tributyl acetylcitrate	630
1,2-Propanedithiol	536		

<sup>1</sup> N, new specification prepared; R, existing specification revised; S, specification exists, revision not considered or required; T, the existing new or revised specification is tentative and information is needed; W, existing specification withdrawn.

<sup>2</sup> A specification was developed for furfuryl butyrate, but its safety was not assessed because the Committee had no information relating to its intake.

<sup>3</sup> Group ADI of 0-0.5 mg/kg bw for furfural, furfuryl alcohol, furfuryl acetate, furfuryl propionate, furfuryl pentanoate, furfuryl octanoate, furfuryl 3-methylbutanoate, methyl 2-furoate, propyl 2-furoate, amyl 2-furoate, hexyl 2-furoate, and octyl 2-furoate that was established at the present meeting.

<sup>4</sup>An ADI of 0-0.4 mg/kg bw was established for 2-phenylphenol by the 1999 Joint FAO/WHO Meeting on Pesticide Residues (FAO Plant Production and Protection Paper 153, 1999)

<sup>5</sup>The existing specification for each of these flavouring agents was revised and the "tentative" designation was deleted.



### 3. Contaminants

#### A. Cadmium

The provisional tolerable weekly intake (PTWI) of 7 µg/kg bw was maintained. Ranges of predicted dietary intakes that may be associated with excess prevalence of renal tubular dysfunction were estimated as described in the following table, which can be used to provide an indication of risk at various levels of exposure for potentially sensitive groups within the population. See Table 2 for recommended studies.

#### ***Relationship between urinary cadmium excretion at steady state and predicted excess prevalence of renal tubular dysfunction<sup>1</sup>***

Scenario	Urinary excretion (µg Cd/g creatinine) <sup>2</sup>	Predicted Cd intake (µg/day) <sup>3</sup>	Predicted Cd intake (µg/kg bw per day) <sup>3,4</sup>	Predicted excess prevalence of renal tubular dysfunction in the population (%) <sup>2</sup>
1. Ratio of dietary Cd intake to urinary excretion = 12	2.5	30	0.5	0
10% bioavailability of Cd in the diet	4.2	50	0.8	4
100% absorbed Cd is excreted in the urine	8.2	100	1.7	20
2. Ratio of dietary Cd intake to urinary excretion = 24	2.5	60	1.0	0
10% bioavailability of Cd in the diet	4.2	100	1.7	4
50% absorbed Cd is excreted in the urine	8.2	200	3.3	20
3. Ratio of dietary Cd intake to urinary excretion = 48	2.5	120	2.0	0
5% bioavailability of Cd in the diet	4.2	200	3.3	4
50% absorbed Cd is excreted in the urine	8.2	400	6.7	20

<sup>1</sup>Assumes no significant changes in cadmium dietary intake over time and excretion of 1.2 g creatinine per day. Details of the calculations and the basis for them will be included in the report and toxicological monograph that will be published later.

<sup>2</sup>These values were derived primarily from studies relating to occupational exposure to cadmium.

<sup>3</sup>Cadmium intake that corresponds to its urinary excretion under the chosen scenario.

<sup>4</sup>Assumed body weight is 60 kg. The PTWI corresponds to a daily intake of 1 µg/kg bw.

#### B. Tin

The provisional tolerable weekly intake (PTWI) of 14 mg/kg bw was not reconsidered and was maintained. The Committee assessed the acute toxicity of tin, but data were insufficient for establishing an acute reference dose. It reiterated the conclusion that it reached at the thirty-third meeting (WHO Technical Report Series No. 776, 1989) that tin concentrations as low as 150 mg/kg in canned beverages and 250 mg/kg in other canned foods may produce acute manifestations of gastric irritation in certain individuals.

#### 4. Food additives considered for specifications only

##### A. Food additives for revision of specifications for identity and purity

Food additive	Specifi- cation <sup>1</sup>	Food additive	Specifi- cation <sup>1</sup>
$\alpha$ -Amylase and glucoamylase from <i>Aspergillus oryzae</i> , var	R	2-Nitropropane <sup>2</sup>	W
$\alpha$ -Amylase from <i>Aspergillus oryzae</i> , var	R	Oxystearin <sup>3</sup>	R,T
Amyloglucosidase from <i>Aspergillus niger</i> , var <sup>3</sup>	R,T	Pectinase from <i>Aspergillus niger</i> , var	R
Blackcurrant extract <sup>3</sup>	R,T	Pentasodium triphosphate	R
Cellulase from <i>Penicillium funiculosum</i>	R	Protease from <i>Aspergillus oryzae</i> , var	R
Cochineal extracts	R	Quillaia extracts	R
Curcumin	R	Shellac, bleached	R
Diethyl ether	R	Smoked flavourings <sup>3</sup>	R,T
$\beta$ -Glucanase from <i>Trichoderma harzianum</i>	R	Sodium sulfate	R
Guaiac resin	R	Sorbitan monolaurate	R
Hemicellulase from <i>Aspergillus niger</i> , var	R	Tagetes extract <sup>3</sup>	R,T
Microcrystalline cellulose	R	Talc	R
Microcrystalline wax	R	D- $\alpha$ -Tocopherol concentrate	R
		Trichloroethylene <sup>4</sup>	W

##### B. Food additives for which previous specifications were designated as tentative

Food additive	Specifi- cation	Food additive	Specifi- cation
Acetone peroxides <sup>5</sup>	W	Carbohydrase from <i>Aspergillus awamori</i> , var <sup>5</sup>	W
Aluminium potassium sulfate <sup>6</sup>	R	Chlorine dioxide <sup>5</sup>	W
Aluminium sodium sulfate <sup>5</sup>	W	Diatomaceous earth <sup>6</sup>	R
Aluminium sulfate (anhydrous) <sup>6</sup>	R	Diethyl pyrocarbonate <sup>5</sup>	W
Ammonium persulfate <sup>5</sup>	W	Isoamyl gallate <sup>5</sup>	W
Ammonium salts of phosphatidic acid <sup>6</sup>	R	Lipase from <i>Aspergillus oryzae</i> , var <sup>5</sup>	W
Benzoin gum <sup>5</sup>	W	Potassium persulfate <sup>5</sup>	W
Calcium iodate <sup>5</sup>	W	Rennet from <i>Endothia parasitica</i> <sup>5</sup>	W
Calcium peroxide <sup>5</sup>	W	Rennet from <i>Rhizomucor</i> species ( <i>Mucor</i> species) <sup>6</sup>	R
Carbohydrase from <i>Aspergillus oryzae</i> , var <sup>5</sup>	W		

<sup>1</sup>N, new specification prepared; R, existing specification revised; T, the existing new or revised specification is tentative and information is needed; W, existing specification withdrawn.

<sup>2</sup>The temporary acceptance of 2-nitropropane for use as a fractionating solvent in the production of fats and oils was not extended at the thirty-fifth meeting of the Committee (WHO Technical Report Series, No. 789, 1990). In the absence of further information on use, the Committee withdrew the specification.

<sup>3</sup>See Table 2.

<sup>4</sup>At its twenty-seventh meeting (WHO Technical Report Series, No. 696, 1983), the Committee recommended that the use of trichloroethylene as an extraction solvent should be limited in order to ensure that its residues in food are as low as practicable. The Committee withdrew the specification because requested information on the nature, level(s), and methods of analysis for stabilizers in food-grade trichloroethylene, assay requirements, method of assay, and requirements and methodology for volatile impurities were not provided.

<sup>5</sup>Relevant information was not provided so the tentative specification was withdrawn.

<sup>6</sup>The specification was revised and the "tentative" designation was deleted.

## Table 2

### Further information required or desired

#### **A. Toxicological information**

##### **D-Tagatose**

Before reviewing the compound again, the Committee would wish to evaluate two final reports of studies in Wistar and Sprague-Dawley rats that were available in draft form that might contribute to resolution of the issues surrounding liver glycogen deposition and hypertrophy, and data to clarify the extent, mechanism, and toxicological consequences of increased uric acid concentrations observed in human subjects.

##### **Cadmium**

The Committee recommended that the following studies be performed to improve confidence in estimates of predicted excess prevalence of renal tubular dysfunction:

- toxicokinetics of cadmium in controlled human experimental studies addressing the relationship between dietary cadmium intake and urinary excretion of cadmium in the general population and high-risk groups (i.e. those who are iron deficient or have renal disease or diabetes mellitus);
- dietary surveys that collect individual records of food consumption for specific population groups;
- bioavailability of cadmium from specific foods and factors that influence bioavailability, such as age, health status, and dietary nutrients;
- the relationship between biomarkers of renal tubular dysfunction and biomarkers of exposure;
- the relationship between renal tubular dysfunction (as determined by specific biomarkers), clinical disease, and mortality;
- the influence of cadmium on calcium metabolism and osteoporosis; and
- the role of integrated cadmium exposure over a lifetime on the development of osteoporosis later in life.

#### **B. Information on specifications**

##### **Amyloglucosidase from *Aspergillus oryzae*, var**

Information is required on the assay for amyloglucosidase in formulated products with glucose. Comments on other aspects of the monograph are also invited.

##### **Blackcurrent extract**

Information is required on the chromatographic identification test and adequacy of the sample size for the sulfur dioxide test. Comments on other aspects of the monograph are also invited.

##### **Oxystearin**

Information on the levels of epoxides and suitable methods for the determination of epoxides is required for consideration at the fifty-seventh meeting of JECFA in June 2001. Comments on other aspects of the monograph are also invited.

##### **Smoked flavourings**

Information is required on an alternative solvent to benzene in the method of analysis for carbonyls (proposals should be supported by a comparative test of the method with benzene and the proposed alternative solvent). Comments on other sections of the monograph are also invited.

##### **Tagates extract**

Information is required on the composition of commercial products, description, a test for identification of xanthophylls, and the method of assay. Comments on other sections of the monograph are also invited.

## Annex 1

### General considerations and issues relating to specifications

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

#### Need for data

Three food additives were placed on the agenda of the meeting of the present Committee on the basis of referrals from the Codex Committee on Food Additives and Contaminants to consider uses in the draft General Standard for Food Additives. The Committee was asked to consider the use of benzoyl peroxide in milk products, the use of nitrous oxide as a packaging gas, and of stearyl tartrate both as an emulsifier, and as a flour treatment agent at a higher level than previously specified by JECFA. Although the specifications for these three substances were updated, no evidence for the use of stearyl tartrate could be found and none of these substances could be toxicologically evaluated because relevant information was not provided.

While the Expert Committee wishes to be responsive to the requests of the Codex Committee, it emphasizes that it can evaluate substances only if relevant data on toxicology and intake are provided. The Committee therefore requested the Codex Committee on Food Additives and Contaminants to ensure that the necessary data are available before referring a substance for consideration by the Expert Committee.

#### Emulsifiers: limits for metals

At its fifty-third meeting, the Committee reaffirmed its policy of replacing the outdated test for heavy metals (as lead) with limits for individual metals. On the basis of data received on the organic emulsifiers listed in the following table, the present Committee deleted the limits for arsenic and heavy metals (as lead) and replaced them with a limit for lead of 2 mg/kg in accordance with the principles stated in FAO Food and Nutrition Paper 52, Add 7, Section C.

Information on limits for lead was also received on inorganic phosphates having emulsifier use; however, supporting analytical data were not provided. The data were sufficient to replace the previous limits for arsenic and lead with limits of 3 mg/kg and 4 mg/kg, respectively, and to delete limits for heavy metals (as lead) for the phosphate emulsifiers listed in the following table.

When the limit test for heavy metals (as lead) is replaced with limits for individual metals, the absence of a particular metal from a specification means that the Committee has concluded that the level of contamination is so low as to be of no toxicological concern. Comments on the proposed limits are invited.

**Limits for arsenic and lead in forty-three organic and inorganic phosphate emulsifiers**

INS <sup>1</sup>	Additive	Arsenic (mg/kg)	Lead (mg/kg)
472	Acetic acid esters of mono and diglycerides of fatty acids		2
452v	Ammonium polyphosphate	3	4
442	Ammonium salts of phosphatidic acid		2
452iv	Calcium polyphosphate	3	4
482i	Calcium stearyl-2-lactylate		2
1000	Cholic acid		2
472c	Citric and fatty acid esters acid esters of glycerol		2
	Desoxycholic acid		2
450vi	Dicalcium pyrophosphate (diphosphate)	3	4
480	Diocetyl sodiumsulphosuccinate		2
450i	Disodium pyrophosphate (diphosphate)	3	4
445	Glycerol esters of wood rosin		2
472b	Lactic acid esters of mono and diglycerides of fatty acids		2
322	Lecithin, partially hydrolysed		2
472e,f	Diacetyl tartronic acid esters of glycerol		2
471	Mono and diglycerides of fatty acids		2
475	Polyglycerol esters of fatty acids		2
476	Polyglycerol esters of interesterified ricinoleic acid		2
431	Polyoxyethylene (40) stearate		2
432	Polyoxyethylene sorbitan monolaurate (polysorbate 20)		2
433	Polyoxyethylene sorbitan monooleate (polysorbate 80)		2
434	Polyoxyethylene sorbitan monopalmitate (polysorbate 40)		2
435	Polyoxyethylene sorbitan monostearate (polysorbate 60)		2
436	Polyoxyethylene sorbitan tristearate (polysorbate 65)		2
430	Polyoxyethylene stearate (8)		2
477	Propylene glycol esters of fatty acids		2
470	Salts of fatty acids		2
541ii	Sodium aluminium phosphate, basic	3	4
	Sodium metaphosphate, insoluble	3	4
452i	Sodium polyphosphate, glassy	3	4
481i	Sodium stearyl-2-lactylate		2
494	Sorbitan monooleate		2
495	Sorbitan monopalmitate		2
491	Sorbitan monostearate		2
492	Sorbitan tristearate		2
484	Stearyl citrate		2
	Stearyl monoglyceridyl citrate		2
472g	Succinylated monoglycerides		2
474	Sucroglycerides		2
450v	Tetra potassium pyrophosphate	3	4
450iii	Tetra sodium pyrophosphate	3	4
	Thermally oxidised soya bean oil		2
479b	Thermally oxidized soya bean oil/ glycerides of fatty acids		2

<sup>1</sup>INS: International Numbering System

## Annex 2

### Joint FAO/WHO Expert Committee on Food Additives Geneva, 6-15 June 2000

### 55<sup>th</sup> Joint FAO/WHO Expert Committee on Food Additives Geneva, 6-15 June 2000

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