codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4(b) **CX/FAC 02/3**
January 2002

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-fourth Session
Rotterdam, The Netherlands, 11-15 March 2002

ACTION REQUIRED AS A RESULT OF CHANGES IN ACCEPTABLE DAILY INTAKE (ADI) STATUS AND OTHER TOXICOLOGICAL RECOMMENDATIONS

1. This document summarizes action required by the Codex Committee on Food Additives and Contaminants as a result of changes in the Acceptable Daily Intake (ADI) status of food additives or other toxicological recommendations concerning contaminants as proposed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 57th Meeting (Rome, 5-14 June 2001).[1]

2. At its 57th Meeting, JECFA recommended changes to existing ADIs and/or established new or temporary ADIs or other toxicological recommendations as contained in the attached Table. The CCFAC should decide and agree on any action which might be required concerning these changes.

3. At its 57th Meeting, JECFA also evaluated a large number of flavouring agents using the Procedure for the Safety Evaluation of Flavouring Agents. As JECFA concluded that these substances were of "no safety concern" based on current intake, they are not included in the attached Table.

[1] See the Summary and Conclusions of the 57th Meeting of the Joint FAO/WHO Expert Committee on Food Additives, (Unnumbered, Agenda Item 4a) for additional details.

SUBSTANCE	PREVIOUS ADI AND OTHER TOXICOLOGICAL RECOMMENDATIONS	PRESENT ADI AND OTHER TOXICOLOGICAL RECOMMENDATIONS
Emulsifiers		
Diacetyltartaric and fatty acid esters of glycerol	- ADI withdrawn	- 0-50 mg/kg bw (temporary)[a]
Tartaric, acetic and fatty acid esters of glycerol, mixed	- Not Specified	- ADI withdrawn[b]
Quillaia extracts	- 0-5 mg/kg bw	- 0-5 mg/kg bw (temporary)[c]
Enzyme preparation		
Invertase from *Saccharomyces cerevisiae*	None	Acceptable[d]
Food colours		
β-Carotene from *Blakeslea trispora*	- None	- 0-5 mg/kg bw (group ADI with synthetic β-carotene) [e]
Curcumin	- 0-1 mg/kg bw (temporary)	- 0-1 mg/kg bw (temporary)f
Food salts		
Calcium dihydrogen diphosphate	- None	Included in the maximum tolerable daily intake of 70 mg/kg bw for phosphates, diphosphates, and polyphosphates
Monomagnesium phosphate	- None [g]	
Sodium calcium polyphosphate	- None	
Trisodium diphosphate	- None [g]	
Glazing agent		
Hydrogenated poly-1-decene	No ADI Allocated	0-6 mg/kg bw
Preservative		
Natamycin (pimaricin)	0-0.3 mg/kg bw [h]	0-0.3 mg/kg bw
Sweetening agent		
D-Tagatose	No ADI Allocated	0-80 mg/kg bw
Thickening agents		
Carrageenan	- Not Specified (Temporary).	ADI "not specified"[h] (group ADI for carrageenan and processed *Eucheuma* seaweed)
Processed *Eucheuma* seaweed	- Not Specified (Temporary).	
Curdlan	- Not Specified (ADI Temporary).	ADI "not specified"[h]
Miscellaneous substances		
Acetylated oxidized starch	- None[j]	- ADI "not specified"[I]
α-Cyclodextrin	- None	- ADI "not specified"[I]
Sodium sulfate	- Not Specified (Temporary).	- ADI "not specified"[I]
Contaminant		
3-Chloro-1,2-propanediol	Levels in hydrolysed vegetable protein should be reduced as far as technically possible	PMTDI (provisional maximum tolerable daily intake): 2 μg/kg bw
1,3-Dichloro-2-propanol	Levels in hydrolysed vegetable protein should be reduced as far as technically possible	Establishment of a tolerable intake was considered to be inappropriate because of the nature of toxicity (tumorogenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA); The Committee noted that the dose that caused tumours in rats (19 mg/kg bw per day) was about 20 000 times the highest estimated intake of 1,3-dichloro-2-propanol by consumers of soya sauce (1 μg/kg bw per day).

Polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and dioxin-like polychlorinated biphenyls (PCBs)	None	PTMI (provisional tolerable monthly intake): 70 pg/kg bw[k]

[a] At the fifty-first meeting (1998), the 1997 specifications for tartaric, acetic and fatty acid esters of glycerol, mixed were withdrawn and merged with the existing 1997 specifications for diacetyltartaric and fatty acid esters of glycerol. As specifications no longer existed for tartaric, acetic and fatty acid esters of glycerol, mixed, its ADI of "NOT SPECIFIED" was withdrawn at the fifty-seventh meeting (2001).

[b] The ADI was withdrawn because the specifications for tartaric, acetic and fatty acid esters of glycerol, mixed, were combined with those of diacetyltartaric and fatty acid esters of glycerol under the latter name at the fifty-first meeting (WHO Technical Report Series, No. 891, 2000).

[c] The existing specifications for quillaia extracts were revised in order to clarify the differences between unpurified and semi-purified extracts Additional information on composition (minimum and maximum percentages of saponins unpurified and semi-purified extracts) is necessary, so the specifications were designated as tentative. Once the requested information has been received, the Committee will consider whether separate specifications for unpurified and semi-purified extracts are required. This information is required for evaluation in 2003. The ADI was made temporary pending clarification of the specifications. The temporary ADI is applicable only to the unpurified extract.

[d] Invertase from *Saccharomyces cerevisiae* that meets the specifications developed at the present meeting was considered to be acceptable because *S. cerevisiae* is commonly used in the preparation of food. Its use should be limited by Good Manufacturing Practice.

[e] Information is required on the method of analysis for residual solvents (ethyl acetate and isobutyl acetate). This information is required for evaluation in 2003

[f] The results of a reproductive toxicity study on a substance complying with the specifications for curcumin, known to be in progress, is required for evaluation in 2003

[g] Information is required on the loss on drying, loss on ignition, test method for loss on ignition and assay method for the hydrates. This information is required for evaluation in 2003.

[h] Information is required on the level and determination of water content, lead limit, specific rotation, assay value and method of assay for the commercial product. Comments on other aspects of the monograph are invited. This information is required for evaluation in 2003.

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

[j] The new specifications for Acetylated Oxidized Starch were integrated into the revised specifications for Modified Starches

[k] the long half-times of PCDDs, PCDFs, and coplanar PCBs result in each daily ingestion having a small or even negligible effect on overall intake. Only after consideration of the total or average intake of PCDDs, PCDFs, and coplanar PCBs over months can their long- or short-term risk to health be assessed. The tolerable intake should therefore be assessed over 1 month or longer. To encourage this view, the Committee decided to express the tolerable intake as a monthly value in the form of a *provisional tolerable monthly intake* (PTMI).