codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4(b) **CX/FAC 05/37/4**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, The Netherlands, 25 – 29 April 2005

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

1. This document summarizes actions 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 natural food constituents and contaminants as proposed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at its 63rd Meeting (Geneva, 8-17 June 2004) and the at its 64th meeting (Rome, 8-17 February 2005).[1, 2]

2. At its 63rd Meeting, JECFA recommended changes to existing ADIs and/or established new or temporary ADIs or gave other toxicological recommendations for food additives and ingredients as contained in the attached Table 1. The CCFAC should decide and agree on any action which might be required concerning these changes.

3. At its 63rd 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 (with the exception of d-Limonene, for which the previously established ADI 'not specified' was maintained), they are not included in the attached Table 1.

4. In addition, at its 63rd Meeting, JECFA also evaluated a natural constituent of food, glycyrrhizinic acid and the toxicological conclusion is included in Table 2.

5. At its 64th Meeting, JECFA evaluated a number of food contaminants, acrylamide, cadmium, ethyl carbamate, inorganic tin, polybrominated diphenyl ethers, and polycyclic aromatic hydrocarbons. The evaluations and recommendations are included in Table 3. The CCFAC should decide and agree on any action which might be required concerning these recommendations.

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1 See the Summary and Conclusions of the 63rd Meeting of the Joint FAO/WHO Expert Committee on Food Additives, (Unnumbered, Agenda Item 4a) for additional details.

2 See the Summary and Conclusions of the 64th Meeting of the Joint FAO/WHO Expert Committee on Food Additives, (Unnumbered, Agenda Item 4a) for additional details

Table 1. Food additives evaluated toxicologically at the 63rd JECFA meeting

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFAC
928	Benzoyl peroxide	Treatment of whey with benzoyl peroxide at a maximum concentration of 100 mg/kg does not pose a safety concern.	Consider to draft an entry in GSFA or classify as processing aid.
-	α-Cyclodextrin	α-Cyclodextrin does not pose a safety concern at the proposed use levels[3] and resulting predicted consumption as food ingredient and food additive. The previously established ADI "not specified" for use as a carrier and stabilizer for flavours, colours, and sweeteners, as a water-solubilizer for fatty acids and certain vitamins, as a flavour modifier in soya milk, and as an absorbent in confectionery was maintained.	No action required.
-	Hexose oxidase from *Chondrus crispus* expressed in *Hansenula polymorpha*	Not specified	i) Determine if substance is a food additive or a processing aid. ii) If food additive include in GSFA.
-	Lutein from *Tagetes erecta* L.	0–2 mg/kg bw (group ADI for lutein and zeaxanthin)[4]	Proceed to consider draft entries in GSFA Consider adoption of an INS number.

[3] The intended use levels from the proposed new use of α-cyclodextrin as an ingredient in a number of food products range from a maximum of 10 g/kg in non alcoholic beverages to a maximum of 100 g/kg in bakery products.

[4] This group ADI does not apply to other xanthophylls-containing extracts with lutein or zeaxanthin content lower than that cited in the specifications (Not less than 80% total carotenoids, not less than 70% lutein)

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFAC
-	Peroxyacid antimicrobial solutions containing 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) *Containing HEDP and three or more of the following components: peroxacetic acid, acetic acid, hydrogen peroxide, octanoic acid and peroxyoctanoic acid.*	The peroxy compounds in these solutions (hydrogen peroxide, peroxyacetic acid and peroxyoctanoic acid) would break down into acetic acid and octanoic acid, and small residual quantities of these acids on foods at the time of consumption would not pose a safety concern. HEDP does not pose a safety concern at the levels of residue that are expected to remain on foods at the time consumption	Consider whether processing aid or food additive and discuss corresponding follow-up action.
-	Steviol glycosides	0–2 mg/kg bw (temporary)	No action.
-	D-Tagatose	Not specified	Consider to draft an entry in GSFA
-	Xylanase from *Bacillus subtilis* expressed in *Bacillus subtilis*	Not specified	i) Determine if substance is a food additive or a processing aid. ii) If food additive include in GSFA
-	Xylanase (resistant to xylanase inhibitor) from *Bacillus subtilis* containing a modified xylanase gene from *Bacillus subtilis*	Not specified	i) Determine if substance is a food additive or a processing aid. ii) If food additive include in GSFA
-	Zeaxanthin (synthetic)	0–2 mg/kg bw (group ADI for lutein and zeaxanthin)[5]	Proceed to consider draft entries in GSFA Consider adoption of an INS number.

[5] This group ADI does not apply to other xanthophylls-containing extracts with lutein or zeaxanthin content lower than that cited in the specifications (Not less than 96%)

Table 2. Natural constituent evaluated toxicologically at the 63rd JECFA meeting

Contaminant	Tolerable intake and other toxicological recommendations	Recommended action by CCFAC
Glycyrrhizinic acid	Available data suggest that an intake of 100 mg per day would be unlikely to cause adverse effects in the majority of adults. In certain highly susceptible individuals, physiological effects could occur at exposure levels somewhat below this figure. The intake data indicate that consumers with a high intake of liquorice confectionery or herbal tea containing liquorice may be exposed to glycyrrhizinic acid at more than 100 mg/day.	No action suggested by JECFA - possible discussion about follow-up.

Table 3. Contaminants evaluated toxicologically at the 64th JECFA meeting

Contaminant	Tolerable intake and other toxicological recommendations	Recommended action by CCFAC
Acrylamide	See Summary report under agenda item 4 (a)	Consider developing a code of practice to reduce acrylamide concentrations in foodstuffs.
Cadmium – Impact assessment of different MLs	The Committee concluded that the effect of different MLs on overall intake of cadmium would be very small. At the proposed Codex MLs, mean intake of cadmium would be reduced by approximately 1% of the PTWI. See Summary report under agenda item 4 (a)	Consider to discontinue consideration of MLs for cadmium in some or all commodities
Ethyl carbamate	See Summary report under agenda item 4 (a)	Consider developing a code of practice to reduce ethylcarbamate in alcoholic beverages, particularly in stone fruit brandies
Inorganic Tin	The Committee reiterated that inorganic tin at concentrations of > 150 mg/kg in canned beverages or 250 mg/kg in canned foods may produce acute manifestations of gastric irritation in certain individuals. Therefore ingestion of reasonably-sized portions containing inorganic tin at concentrations equal to the proposed standard for canned beverages (200 mg/kg) may lead to adverse reactions. See Summary report under agenda item 4 (a)	Consider modification of the MLs for inorganic Tin in canned beverages at Step 4.
Polybrominated diphenyl ethers	The Committee noted that despite the inadequacy of the data on toxicity and intake, there is some reassurance that intakes of PBDEs are not likely to be a significant health concern. See Summary report under agenda item 4 (a)	No action
Polycyclic aromatic hydrocarbons	The Committee concluded that the critical effect of PAH is carcinogenicity. The Committee decided to apply a surrogate approach to the evaluation, in which benzo[a]pyrene was used as a marker of exposure to, and effect of, the 13 genotoxic and carcinogenic PAHs. The Committee concluded that the estimated intakes of PAHs were of low concern for human health. See Summary report under agenda item 4 (a)	Consider appropriate source directed measures to reduce contamination with PAHs during drying and smoking processes.