

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4(b)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-sixth Session

Rotterdam, The Netherlands, 22 – 26 March 2004

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 61st Meeting (Rome, 10-19 June 2003).¹
2. At its 61st 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 61st 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.
4. At its 61st Meeting, JECFA recommended no changes to the existing PTWI for cadmium and established a new PTWI for methylmercury as contained in the attached Table. The CCFAC should decide and agree on any action which might be required concerning these changes.

¹ See the Summary and Conclusions of the 61st Meeting of the Joint FAO/WHO Expert Committee on Food Additives, (Unnumbered, Agenda Item 4a) for additional details.

1. Food additives evaluated toxicologically

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFAC
160b	Annatto extract (solvent-extracted bixin)	0 – 7 mg/kg bw (temporary); for preparations containing not less than 85 % pigment (as bixin, of which not more than 2.5% is norbixin)	No action. Await further JECFA consideration of temporary ADI
160b	Annatto extract (solvent-extracted norbixin)	0 – 0.4 mg/kg bw (temporary); for preparations containing not less than 85% pigments (as norbixin)	No action. Await further JECFA consideration of temporary ADI
160b	Annatto extract (oil-processed bixin suspension)	No ADI established, since no data on toxicity were available	No action.
160b	Annatto extract (aqueous-processed bixin)	0 – 4 mg/kg bw (temporary); for a preparations containing not less than 25% pigments (as bixin, of which not more than 7% is norbixin)	No action. Await further JECFA consideration of temporary ADI
160b	Annatto extract (alkali-processed norbixin)	0 – 0.4 mg/kg bw (temporary); for a preparation containing not less than 35% pigments (as norbixin)	No action. Await further JECFA consideration of temporary ADI
160b	Annatto extract (alkali-processed norbixin, not acid-precipitated)	No ADI established, since no data on toxicity were available	No action.
100i	Curcumin	0-3 mg/kg bw	Proceed to consider draft entries in GSFA Tables 1 and 2 at step 6
472e	Diacetyltartaric and fatty acid esters of glycerol (DATEM)	0-50 mg/kg bw	Proceed to consider draft entries in GSFA Tables 1 and 2 at step 6
-	Alpha-amylase from <i>Bacillus licheniformis</i> containing a genetically engineered alphaamylase gene from <i>B. licheniformis</i>	Not specified	i) Determine if substance is a food additive ² or a processing aid. ii) If food additive include in GSFA Table 3. iii) consider whether this enzyme should be included in the INS no. 1100

² The International Numbering System for Food Additives lists 1100 Amylases only as Flour Treatment Agents. CCFAC may consider other uses to be more appropriately classed as processing aids functions.

INS Number	Food additive	Acceptable daily intake (ADI) and other toxicological recommendations	Recommended action by CCFAC
-	Laccase from <i>Myceliophthora thermophila</i> expressed in <i>Aspergillus oryzae</i>	Not specified	i) Determine if substance is a food additive ³ or a processing aid. ii) If food additive include in GSFA Table 3.
-	Mixed xylanase, β -glucanase enzyme preparation, produced by a strain of <i>Humicola insolens</i>	Not specified	i) Determine if substance is a food additive ³ or a processing aid. ii) If food additive include in GSFA Table 3.
-	Xylanase from <i>Thermomyces lanuginosus</i> expressed in <i>Fusarium venenatum</i>	Not specified	i) Determine if substance is a food additive ³ or a processing aid. ii) If food additive include in GSFA Table 3.
961	Neotame	0 – 2 mg/kg bw	Request data on proposed uses for inclusion in GSFA Tables 1 and 2 at Step3
	Polyvinyl alcohol	0–50 mg/kg bw	i) Request data on proposed uses for inclusion in GSFA Tables 1 and 2 at Step 3 ii) Consider the adoption of an INS number
999	Quillaia extract (Type 1)	0 – 5 mg/kg bw	Ensure proposed draft entries in GSFA Tables 1 and 2 are compatible with material meeting Type 1 specification
-	Quillaia extract (Type 2)	No ADI established due to limited information on the qualitative and quantitative composition	No action. Await further JECFA consideration
-	D-Tagatose	0 – 125 mg/kg bw (temporary)	No action. Await further JECFA consideration of temporary ADI

³ Laccase, Xylanase and β -Glucanase are not currently listed in the International Numbering System for Food Additives.

2. Contaminants evaluated toxicologically

Contaminant	Tolerable intake and other toxicological recommendations	Recommended action by CCFAC
Cadmium	Provisional tolerable weekly intake (PTWI) of 7 µg/kg bw (maintained)	Continue consideration of MLs for cadmium in various commodities at Step 3. The Committee also provided advice on those commodities contributing the most to the overall dietary exposure to Cadmium, as requested at the 35 th CCFAC.
Methyl mercury	Provisional tolerable weekly intake (PTWI) of 1.6 µg/kg bw	CCFAC may wish to examine CAC/GL 7-191 Guideline Levels for Methyl mercury in Fish in the light of the new PTWI.