



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx COMMITTEE ON FOOD ADDITIVES

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ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES AND PROCESSING AIDS IN CODEx STANDARDS

BACKGROUND

1. In accordance with the section concerning Relations between Commodity Committees and General Committees of the Codex Alimentarius Commission Procedural Manual, "*All provisions in respect of food additives (including processing aids) contained in Codex commodity standards should be referred to the Committee on Food Additives, preferably before the Standards have been advanced to Step 5 of the Procedure for the Elaboration of Codex Standards or before they are considered by the commodity committee concerned at Step 7, though such referral should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.*".

2. The following food additive and processing aids provisions of Codex standards have been submitted for endorsement since the 48th Session of the Codex Committee on Food Additives and are listed by:

- (i) Technological function, INS number and food additive name;
- (ii) Maximum level;
- (iii) ADI (mg additive/kg body weight per day); and
- (iv) Notes.

3. The following abbreviations have been used in the preparation of this paper:

INS International Numbering System for food additives. The INS (INS) is intended as a harmonised naming system for food additives as an alternative to the use of the specific name, which may be lengthy¹.

ADI Acceptable Daily Intake. An estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk (standard human = 60 kg)². The ADI is listed in units of mg per kg of body weight.

ADI "Not Specified". A term applicable 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 JECFA, represent a hazard to health. For that reason, and for reasons stated in individual evaluations, the establishment of an acceptable daily intake 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 inferior food quality or adulteration, and it should not create a nutritional imbalance².

ADI "Not Limited". A term no longer used by JECFA that has the same meaning as ADI "not specified"².

¹ *Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989)

² JECFA Glossary of terms:

http://apps.who.int/iris/bitstream/10665/44065/13/WHO_EHC_240_13_eng_Annex1.pdf?ua=1

Temporary ADI. Used by JECFA when data are sufficient to conclude that use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data, but are insufficient to conclude that use of the substance is safe over a lifetime. A higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA. The temporary ADI is listed in units of mg per kg of body weight².

Conditional ADI. A term no longer used by JECFA to signify a range above the "unconditional ADI" which may signify an acceptable intake when special problems, different patterns of dietary intake, and special groups of the population that may require consideration are taken into account².

No ADI allocated. There are various reasons for not allocating an ADI, ranging from a lack of information to data on adverse effects that call for advice that a food additive or veterinary drug should not be used at all. The report should be consulted to learn the reasons that an ADI was not allocated².

Acceptable².

Flavouring agents: Used to describe flavouring agents that are of no safety concern at current levels of intake and subsequent reports of meetings on food additives. If an ADI has been allocated to the agent, it is maintained unless otherwise indicated.

Enzyme preparations: Used to describe enzymes that are obtained from edible tissues of animals or plants commonly used as foods or are derived from microorganisms that are traditionally accepted as constituents of foods or are normally used in the preparation of foods. Such enzyme preparations are considered to be acceptable provided that satisfactory chemical and microbiological specifications can be established.

Food additives: Used on some occasions when present uses are not of toxicological concern or when intake is self-limiting for technological or organoleptic reasons.

Acceptable Level of Treatment. ADIs are expressed in terms of mg per kg of body weight per day. In certain cases, however, food additives are more appropriately limited by their levels of treatment. This situation occurs most frequently with flour treatment agents. It should be noted that the acceptable level of treatment is expressed as mg/kg of the commodity. This should not be confused with an ADI².

Good Manufacturing Practice (GMP) in the Use of Food Additives³ means that:

- the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical nutritional or other technical effect in food;
- the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;
- the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.

³ Procedural Manual of the Codex Alimentarius Commission (Definitions)

**ENDORSEMENT AND/OR REVISION OF MAXIMUM LEVELS FOR FOOD ADDITIVES
IN COMMODITY STANDARDS**

The Committee **is invited to consider for endorsement** the food additive provisions (see Annex 1) forwarded by:

- I. The 28th Session of the Committee on Processed Fruits and Vegetables (CCPFV28) ([REP17/PFV](#)) related to:
 - Proposed Draft Annex on Canned Pineapple (for inclusion in the *Standard for Certain Canned Fruits* (CODEX STAN 319-2015)) (at Step 5/8)
 - Proposed Draft Annexes for Certain Quick Frozen Vegetables (for inclusion in the *Standard for Quick Frozen Vegetables* (CODEX STAN 320-2015)) (at Step 5/8)
 - Annex I: Broccoli
 - Annex II: Brussels Sprouts
 - Annex III: Cauliflower
 - Annex IV: French Fried Potatoes
 - Annex V: Green Beans and Wax Beans
 - Annex VI: Peas
 - Annex VII: Spinach
 - Amendments to food additive provisions in the *Standard for Canned Chestnuts and Canned Chestnut Puree* (CODEX STAN 145-1985)
 - Amendments to food additive provisions in the *Standard for Pickled Fruits and Vegetables* (CODEX STAN 260-2007)
- II. The 20th FAO/WHO Coordinating Committee for Asia (CCASIA20) ([REP17/ASIA](#)) related to:
 - Amendments to food additive provisions in the *Regional Standard for Non-Fermented Soybean Products* (CODEX STAN 322R-2015)
 - The proposed draft Regional Standard for Laver Products (at Step 5/8)
- III. The 20th FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC20) ([REP17/LAC](#)) related to:
 - The proposed draft Regional Standard for Yacon (at Step 5/8)

I. CCPFV28

PROPOSED DRAFT ANNEX ON CANNED PINEAPPLE (FOR INCLUSION IN THE STANDARD FOR CERTAIN CANNED FRUITS (CODEX STAN 319-2015)) (at Step 5/8)⁴

	Note
<p>3. FOOD ADDITIVES</p> <p>3.1 Antifoaming agents and antioxidants used in accordance with Tables 1 and 2 of the <i>General Standard for Food Additives</i> (CODEX STAN 192-1995) in Food Category 04.1.2.4 (Canned or bottled (pasteurized) fruit) or listed in Table 3 of the General Standard are acceptable for use in foods conforming to this Annex.</p>	For info only.
<p>3.2 Flavourings used in products covered by this Annex shall comply with the <i>Guidelines for the Use of Flavourings</i> (CAC/GL 66-2008).</p>	Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards)
	<p>Please note: The general reference to GSFA is applicable only if CCFA has agreed to the CCPFV28 proposal to reflect in the GSFA that “polydimethylsiloxane (INS 900a) and ascorbic acid, L- (INS 300) were respectively the only antifoaming agent and only antioxidant agent currently used in canned pineapples” (see Agenda Item 2, CX/FA 17/49/2, paras 28, 29 and 32).</p>

PROPOSED DRAFT ANNEXES FOR CERTAIN QUICK FROZEN VEGETABLES (FOR INCLUSION IN THE STANDARD FOR QUICK FROZEN VEGETABLES (CODEX STAN 320-2015)) (at Step 5/8)⁵

Annex I: Broccoli

	Note
<p>3. FOOD ADDITIVES</p> <p>None permitted.</p>	For info only.

Annex II: Brussels Sprouts

	Note
<p>3. FOOD ADDITIVES</p> <p>None permitted.</p>	For info only.

Annex III: Cauliflower

	Note
<p>3. FOOD ADDITIVES</p> <p>None permitted.</p>	For info only.

⁴ REP17/PFV, App. II

⁵ REP17/PFV, App. IV

Annex IV: French Fried Potatoes

	Note
<p>3. FOOD ADDITIVES Sequestrants used in accordance with Tables 1 and 2 of the <i>General Standard for Food Additives</i> (CODEX STAN 192-1995) in Food Category 0.4.2.2.1 Frozen Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds, are acceptable for use in food conforming to this Standard.</p>	<p>For info only.</p> <p>Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards).</p> <p>Please note: The general reference to GSFA is applicable only if CCFA has agreed to the CCPFV28 proposal to reflect in the GSFA that “that malic acid DL- (INS 296) was listed under sequestrants while in the GSFA no sequestrant function was assigned to malic acid DL- (INS 296)” (see Agenda Item 2, CX/FA 17/49/2, paras 31 and 32).</p>

Annex V: Green Beans and Wax Beans

	Note
<p>3. FOOD ADDITIVES None permitted.</p>	<p>For info only.</p>

Annex VI: Peas

	Note
<p>3. FOOD ADDITIVES 3.1. Flavourings The flavourings used in products covered by this standard shall comply with the <i>Guidelines for the Use of Flavourings</i> (CAC/GL 66-2008).</p>	<p>For info only.</p> <p>Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards).</p>

Annex VII: Spinach

	Note
<p>3. FOOD ADDITIVES None permitted.</p>	<p>For info only.</p>

AMENDMENTS⁶ TO FOOD ADDITIVE PROVISIONS IN THE STANDARD FOR CANNED CHESTNUTS AND CANNED CHESTNUT PUREE (CODEX STAN 145-1985)⁷

	Note
<p>3. FOOD ADDITIVES 3.8 <u>Firming Agents</u></p>	<p>For info only.</p> <p>Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards).</p>

⁶ Existing text recommended for deletion is shown in strikethrough font. Text recommended for addition is shown **bold/underlined** font.

⁷ REP17/PFV, App. IV

Firming agents used in accordance with Tables 1 and 2 of the General Standard for Food Additives (CODEX STAN 192-1995) in Food Category 04.2.2.4 (Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds or listed in Table 3 of the General Standard are acceptable for use for foods conforming to this Annex.

AMENDMENTS⁶ TO FOOD ADDITIVE PROVISIONS IN THE STANDARD FOR PICKLED FRUITS AND VEGETABLES (CODEX STAN 260-2007)⁷

	Note
<p>4 FOOD ADDITIVES Acidity regulators, antifoaming agents, antioxidants, colours, <u>colour retention agents</u>, firming agents, flavour enhancers, preservatives, sequestrants, <u>stabilizers</u> and sweeteners used in accordance with Tables 1 and 2 of the <i>General Standard of Food Additives</i> in the food category in which the individual pickled fruit or vegetable fall into (i.e., one of the following categories: 04.1.2.3, 04.1.2.10, 04.2.2.3, and 04.2.2.7) or listed in Table 3 of the General Standard are acceptable for use in foods conforming to this Standard.</p>	<p>For info only. Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards).</p>

II. CCASIA20

AMENDMENTS⁸ TO FOOD ADDITIVE PROVISIONS IN THE *REGIONAL STANDARD FOR NON-FERMENTED SOYBEAN PRODUCTS (CODEX STAN 322R-2015)*⁹

4.2.2 Composite/ flavoured Soybean Beverages and Soybean-based Beverages

INS No.	Name of the Food Additive	Maximum Level	ADI	Note
Antioxidant				
<u>307a,b,c</u>	<u>Tocopherols</u>	<u>200 mg/kg</u>	Group ADI of 0.15-2 mg/kg bw for dl- α -tocopherol and d- α -tocopherol, concentrate, singly or in combination (30 th JECFA, 1986)	Currently there is no provisions in the GSFA food categories 06.8.1
Flavour enhancer				
508	Potassium chloride	4000 mg/kg		For info only (see CX/FA 17/49/2 para. 12).

PROPOSED DRAFT REGIONAL STANDARD FOR LAVER PRODUCTS (AT STEP 5/8)¹⁰

INS No.	Name of the Food Additive	Maximum Level	ADI	Note
4. FOOD ADDITIVES				
4.1 Dried Laver Products and Roasted Laver Product No food additives are permitted.				For info only.
4.2 Seasoned Laver Products				
Only acidity regulators, anticaking agents, flavour enhancers, sweeteners, thickeners and antioxidants used in accordance with Tables 1 and 2 of the <i>General Standard of Food Additives</i> (CODEX STAN 192-1995) in food categories 04.2.2.2 and 04.2.2.8 or listed in Table 3 of the <i>General Standard for Food Additives</i> are acceptable for use in seasoned laver products (see Section 2.3.3) conforming to this standard.				For info only. Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards).
In addition, the following food additives may be used. Sweeteners				
950	Acesulfame potassium	300 mg/kg	0-15 mg/kg bw (37 th JECFA, 1990)	Currently there is no provisions in both GSFA food categories 04.2.2.2 and 04.2.2.8
4.2.1 Flavourings The flavourings used in these products should comply with the <i>Guidelines for the Use of Flavourings</i> (CAC/GL 66-2008).				For info only. Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards).

⁸ Existing text recommended for deletion is shown in strikethrough font. Text recommended for addition is shown **bold/underlined** font.

⁹ REP17/ASIA, Part 2 to App. III

¹⁰ REP17/ASIA, Part 2 to App. IV

III. CCLAC20**PROPOSED DRAFT REGIONAL STANDARD FOR YACON (At Step 5/8)¹¹**

	Note
8 FOOD ADDITIVES This Standard applies to yacon as identified in Food Category 04.2.1.1 Untreated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed and nuts and seeds, and therefore no food additives is allowed in accordance with the provisions of the <i>General Standard for Food Additives</i> (CODEX STAN 192-1995).	For info only.

¹¹ REP17/LAC, App. III