CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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**Agenda Item 4(a)** **CX/FA 20/52/5**

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FOOD ADDITIVES**

**Fifty-second Session**

# 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 50th 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 lengthy[1].

**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 imbalance[2].

**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* (CXG 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 weight[2].

**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 account[2].

**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 allocated[2].

**Acceptable[2]**.

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 ADI[2].

**Good Manufacturing Practice (GMP) in the Use of Food Additives** [3] 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:

- the 23rd Session of the FAO/WHO Coordinating Committee for Africa (REP20/AFRICA) related to:
    - Draft regional standard for fermented cooked cassava-based products (at Step 8)
- the 15th Session of the FAO/WHO Coordinating Committee for North America and the South West Pacific (REP20/NASWP) related to:
    - Proposed draft regional standard for fermented noni fruit juice (at Step 5)
    - Proposed draft regional standard for kava products for use as a beverage when mixed with water (at Step 5)
- the 10th Session of the FAO/WHO Coordinating Committee for the Near East (REP20/CCNE) related to:
    - Draft regional standard for mixed zaatar (at Step 8)
- the 41st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (REP20/NFSDU) related to:
    - Proposed Draft Guidelines for Ready to Use Therapeutic Foods (RUTF) (at Step 5)

## CCAFRICA

### DRAFT REGIONAL STANDARD FOR FERMENTED COOKED CASSAVA-BASED PRODUCTS (at Step 8)[4]

| | |
|---|---|
| 4 FOOD ADDITIVES<br>No additives are permitted for use in this product. | For info only |

## CCNASWP

### PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED NONI FRUIT JUICE (at Step 5)[5]

| | |
|---|---|
| 4 FOOD ADDITIVES<br>No additives are permitted in the product as defined by the scope. | For info only |

### PROPOSED DRAFT REGIONAL STANDARD FOR KAVA PRODUCTS FOR USE AS A BEVERAGE WHEN MIXED WITH WATER (at Step 5)[6]

| | |
|---|---|
| 4 FOOD ADDITIVES<br>No additives are permitted in the products covered by this standard. | For info only |

## CCNE

### DRAFT REGIONAL STANDARD FOR MIXED ZAATAR (at Step 8)[7]

4 FOOD ADDITIVES

**Grade 1 and Grade 2 mixed zaatar**

| | |
|---|---|
| No additives are permitted | For info only. |

**Grade 3[8] mixed zaatar[9]**

Only the following food additive is permitted:

[4] REP20/AFRICA, App. III
[5] REP20/NASWP, App. II
[6] REP20/NASWP, App. III
[7] REP20/NE, App. IV
[8] Section 2.2.3 of the draft regional standard describes “Grade 3” Mixed Zaatar “*shall consist of at least 15% raw broadleaf zaatar or raw zaatar mixed with sesame seeds and sumac husk which should be added to a level of at least 5%, with the possibility of adding salt to a maximum level of 4% and citric acid according to Good Manufacturing Practices (GMP). Optional ingredients as listed in section 3.1.2 may be added provided they all meet GMP*.”
[9] CCNE10 explained that citric acid was the only food additive permitted, and recommended mixed zaatar be included in the Food Category 12.2.1 “Herbs and spices”.

| INS No. | Name of the Food Additive | Maximum Level | ADI | Note |
|---|---|---|---|---|
| **Acidity Regulator** | | | | |
| 330 | Citric acid | GMP | Group ADI "Not limited" for citric acid and its calcium, potassium, sodium and ammonium salts (17th JECFA, 1973) | Citric acid is included in GFSA Table 3 and it can be used in spices of food category 12.2.1 under the conditions of good manufacturing practices (GMP) |

## CCNFSDU

**PROPOSED DRAFT GUIDELINES FOR READY TO USE THERAPEUTIC FOODS (RUTF) (at Step 5)[10]**

5.2.2 Food Additives

Only the food additives listed in this Section (Table A: Food Additives in RUTF Formulation) or in the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CXG 10-1979) may be present in the foods described in section 4.1 of this Guideline. Other than by direct addition, an additive may be present in RUTF as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the *General Standard for Food Additives* (CXS 192-1995)

b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the General Standard for Food Additives (CXS 192-1995); and

c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CXS 192-1995).

Only food additives listed in Table A of the guideline are allowed for use in RUTF at the specified maximum use level.

Table A: Food Additives in RUTF Formulation

[10] REP20/NFSDU, App VI

| INS No. | Name of the Food Additive | Maximum Level | ADI | Note |
|---|---|---|---|---|
| **Emulsifier** | | | | |
| 471 | Mono- and di-glycerides of fatty acids | 4000 mg/kg | An ADI not limited (17th JECFA, 1973) | Mono & di-glycerides of fatty acids is included in GFSA Table 3 and it can be used in food category 13.3 "Dietetic foods intended for special medical purposes (excluding products of food category 13.1)" under the condition of GMP |
| 472c | Citric and fatty acid esters of glycerol | 9000 mg/kg | An ADI not limited (17th JECFA, 1973) | Citric and fatty acid esters of glycerol is included in GFSA Table 3 and it can be used in food category 13.3 under the condition of GMP |
| 322(i) | Lecithin | 5000 mg/kg | An ADI not limited (17th JECFA, 1973) | Lecithin is included in GFSA Table 3 and it can be used in food category 13.3 under the condition of GMP |
| **Antioxidant** | | | | |
| 304 | Ascorbyl palmitate | 10 mg/kg | An ADI of 0-1.25 mg/kg bw (17th JECFA, 1973) | Currently there is no ML in GSFA food category 13.3 |
| 307b | Tocopherol concentrate, mixed | 10 mg/kg | A group ADI of 0.15-2 mg/kg bw for dl-α-tocopherol and dα-tocopherol, concentrate, singly or in combination (30th JECFA, 1986) | Tocopherol concentrate, mixed can be used in food category 13.3 at ML 30 mg/kg |
| 300 | Ascorbic acid, L | GMP | A group ADI 'not specified' for ascorbic acid and its Ca, K and Na salts (25th JECFA, 1981) | Ascorbic acid, L is included in GFSA Table 3 and it can be used in food category 13.3 under the condition of GMP |
| **Acidity regulator** | | | | |

| INS No. | Name of the Food Additive | Maximum Level | ADI | Note |
|---|---|---|---|---|
| 330 | Citric acid | GMP | Group ADI "Not limited" for citric acid and its calcium, potassium, sodium and ammonium salts (17th JECFA, 1973) | Citric acid is included in GFSA Table 3 and it can be used in food category 13.3 under the condition of GMP |
| **Packaging gas** | | | | |
| 941 | Nitrogen | GMP | ADI "No ADI necessary" (24th JECFA, 1980) | Nitrogen is included in GFSA Table 3 and it can be used in food category 13.3 under the condition of GMP |
| 290 | Carbon dioxide | GMP | An ADI 'not specified' (29th JECFA, 1985) | Carbon dioxide is included in GFSA Table 3 and it can be used in food category 13.3 under the condition of GMP |
| **Carrier** | | | | |
| 551 | Silicon dioxide, amorphous | 10 mg/kg | An ADI 'not specified' for silicon dioxide and certain silicates (29th JECFA,1985) | Silicon dioxide, amorphous is included in GFSA Table 3 and it can be used in food category 13.3 under the condition of GMP |