CODEX ALIMENTARIUS COMMISSION







Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 4(a)

CX/FA 23/53/5 January 2023

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

Fifty-third 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 52nd 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.

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¹ Class Names and the International Numbering System for Food Additives (CXG 36-1989)

² JECFA Glossary of terms:

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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.

<u>Flavouring agents</u>: 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.

<u>Enzyme preparations</u>: 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.

<u>Food additives</u>: 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 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.

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³ Procedural Manual of the Codex Alimentarius Commission (Definitions)

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

The Committee <u>is invited to consider for endorsement</u> of the food additive provisions (see Annex 1) forwarded by:

- the 22nd Session of the Codex Committee on Fresh Fruits and Vegetables (REP22/FFV) related to:
 - Standard for onions and shallots (adopted by CAC45 at Step 5/8 subject to endorsement of its food labelling and food additive provisions)
 - Standard for berry fruits (adopted by CAC45 at Step 5/8 subject to endorsement of its food labelling and food additive provisions)
 - Standard for fresh dates (adopted by CAC45 at Step 5 subject to endorsement of its food labelling and food additive provisions)
- the 24th Session of the FAO/WHO Coordinating Committee for Africa (REP22/AFRICA) related to:
 - Regional standard for dried meat (adopted by CAC45 at Step 5/8 subject to endorsement of its food labelling and food additive provisions)
- the sixth Session of the Codex Committee on Spices and Culinary Herbs (REP22/SCH) related to:
 - Standard for dried or dehydrated chilli pepper and paprika (adopted by CAC45 at Step 5/8 subject to endorsement of its food labelling and food additive provisions)
 - Standard for dried small cardamom (adopted by CAC45 at Step 5 subject to endorsement of its food labelling and food additive provisions)
 - Standard for spices derived from dried fruits and berries- Allspice, Juniper berry, and Star anise (adopted by CAC45 at Step 5 subject to endorsement of its food labelling and food additive provisions)
- the 22nd Session of the FAO/WHO Coordinating Committee for Asia (REP23/ASIA) related to:
 - Proposed draft regional standard for soybean products fermented with Bacillus species (adopted by CAC45 at Step 5/8 subject to endorsement of its food labelling and food additive provisions)
 - Proposed draft regional standard for cooked rice wrapped in plant leaves (adopted by CAC45 at Step 5/8 subject to endorsement of its food labelling and food additive provisions)
- the 22nd Session of the FAO/WHO Coordinating Committee for Latin America and the Caribbean (REP23/LAC) related to:
 - Insertion of the food additive section in the Regional Standard for Culantro Coyote (CXS 304R-2011)
 - Insertion of the food additive section in the Regional Standard for Lucuma (CXS 305R–2011)

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STANDARD FOR ONIONS AND SHALLOTS (adopted by CAC45 at Step 5/8)⁴

	Note
8. FOOD ADDITIVES	For info only
No food additives are permitted in onions and shallots.	

STANDARD FOR BERRY FRUITS (adopted by CAC45 at Step 5/8)⁵

	Note
8. FOOD ADDITIVES	For info only
No food additives are permitted in berry fruits.	

STANDARD FOR FRESH DATES (adopted by CAC45 at Step 5)⁶

	Note
8. FOOD ADDITIVES	For info only
No food additives are permitted in fresh dates.	

CCAFRICA

REGIONAL STANDARD FOR DRIED MEAT (adopted by CAC45 at Step 5/8)⁷

	Note
4 FOOD ADDITIVES	Text aligned with provisions of the Procedural
Antioxidants, and Preservatives, used in accordance with the <i>General Standard for Food Additives</i> (CXS 192- 1995) in food category 08.2. "Processed meat, poultry, and game products in whole pieces or cuts" and are acceptable for use in foods conforming to this Standard.	Manual (Format for Codex Commodity Standards). Minor editorial changes may be needed.
Use of flavouring substances should be consistent with the Guidelines for the Use of Flavourings (CAC/GL 66- 2008).	

⁴ REP22/FFV, App. II

⁵ REP22/FFV, App. III

⁶ REP22/FFV, App. IV

⁷ REP22/AFRICA, App. III

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STANDARD FOR DRIED OR DEHYDRATED CHILLI PEPPER AND PAPRIKA (adopted by CAC45 at Step 5/8)8

	Note
4 FOOD ADDITIVES	Text aligned with provisions of the Procedural
Anticaking agents listed in Table 3 of the <i>General Standard for Food Additives</i> (CXS 192-1995) are acceptable for use in powdered form of the foods conforming to this standard.	Manual (Format for Codex Commodity Standards)

STANDARD FOR DRIED SMALL CARDAMOM (adopted by CAC45 at Step 5)9

	Note
4 FOOD ADDITIVES The anticaking agents listed in Table 3 of the <i>General Standard for Food Additives</i> (CXS192-1995) may be permitted for use in ground/powdered small cardamom.	Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards). Minor editorial changes may be needed.

STANDARD FOR SPICES DERIVED FROM DRIED FRUITS AND BERRIES- ALLSPICE, JUNIPER BERRY, AND STAR ANISE (adopted by CAC45 at Step 5)¹⁰

	Note
4 FOOD ADDITIVES	Text aligned with provisions of the Procedural
4.1 Anticaking agents listed in Table 3 of the <i>General Standard for Food Additives</i> (CXS 192-1995) are acceptable for use in powdered form of the foods conforming to this standard.	Manual (Format for Codex Commodity Standards)
4.1.1 Processing aids	
The processing aids used in products conforming to this Standard should be consistent with the <i>Guidelines on Substances used as Processing Aids</i> (CXG 75-2010).	

CCASIA

PROPOSED DRAFT REGIONAL STANDARD FOR SOYBEAN PRODUCTS FERMENTED WITH BACILLUS SPECIES (adopted by CAC45 at Step 5/8)¹¹

	Note
4. FOOD ADDITIVES	For info only
None permitted.	

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⁸ REP22/SCH, App V ⁹ REP22/SCH, App VI ¹⁰ REP22/SCH, App VII ¹¹ REP23/ASIA, App VI

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Proposed draft regional standard for cooked rice wrapped in plant leaves (adopted by CAC45 at Step 5/8)¹²

	Note
4 FOOD ADDITIVES Acidity regulators, antioxidants, colours, preservatives and stabilizers used in accordance with Tables 1 and 2 of the General Standard for Food Additives (CXS 192-1995) in food category 06.7 "Pre-cooked or processed rice products, including rice cakes (Oriental type only)" and acidity regulators, antioxidants, colours, preservatives, stabilizers, emulsifiers, flavor enhancers and thickeners, as indicated in Table 3 of the General Standard for Food Additives (CXS 192-1995) are acceptable for use in foods conforming to this Standard.	Text aligned with provisions of the Procedural Manual (Format for Codex Commodity Standards)
The flavourings used in products covered by this standard should comply with the <i>Guidelines for the use of flavourings</i> (CXG 66-2008)	

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INSERTION OF THE FOOD ADDITIVE SECTION IN THE REGIONAL STANDARD FOR CULANTRO COYOTE (CXS 304R-2011) 13

	Note
7. FOOD ADDITIVES	For info only
No food additives are permitted in foods conforming to this standard.	

INSERTION OF THE FOOD ADDITIVE SECTION IN THE REGIONAL STANDARD FOR LUCUMA (CXS 305R-2011)¹³

	Note
7. FOOD ADDITIVES	For info only
No food additives are permitted in foods conforming to this standard.	

¹² REP23/ASIA, App VII ¹³ REP23/LAC, App III