CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4 (a) **CX/FA 16/48/5**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-eighth Session

Xi'an, China, 14-18 March 2016

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 47th Session of the Codex Committee on Food Additives and are listed by:

   (i) Technological function, INS number and food additive name;

   (ii) Proposed 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].

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[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

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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 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 2nd Session of the Committee on Spice and Culinary Herbs (REP16/SCH) related to:

- Proposed Draft Standard for Thyme (at Step 5)

CCSCH2 also advanced to Step 5 the proposed draft Standard for Cumin, which does not allow for the use of food additives and flavourings (REP16/SCH Appendix III).

COMMITTEE ON SPICES AND CULINARY HERBS (CCSCH)

PROPOSED DRAFT STANDARD FOR THYME (At Step 5)[4]

INS No.	Name of the Food Additive	Maximum Level	ADI	Note
4 FOOD ADDITIVES **4.1** Only the anticaking agents listed below are permitted for use in ground/powdered thyme.				
460 (i)	Microcrystalline cellulose	GMP	ADI "Not specified" (49th JECFA, 1998)	These three food additives are included in Table three of the GSFA. Provisions of Table three of the GSFA apply to spices as the Annex to Table 3 lists food category 12.2.1 Herbs and spices and explicitly excludes spices. A number of provisions listed in food category 12.2 and 12.2.1 of the GSFA also apply to herbs and spices.
460 (ii)	Powdered cellulose	GMP	ADI "Not specified" (20th JECFA, 1976)	
551	Silicon dioxide, amorphous	GMP	ADI "Not specified" (29th JECFA, 1985)	

[4] REP16/SCH, App. IV.