

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**Agenda Item 2**

**CX/GP 07/24/2-Add.1**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON GENERAL PRINCIPLES  
Twenty-fourth Session  
Paris, France, 2- 6 April 2007**

**MATTERS REFERRED TO THE COMMITTEE**

**MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER  
CODEX COMMITTEES**

Addendum 1

**Codex Committee on Food Additives and Contaminants**

Proposed Procedure for Consideration of the Entry and Review of Food Additive Provisions in the  
GSFA<sup>1</sup>

The CCFAC agreed to forward the proposed Procedures to the Codex Alimentarius Commission, through the Codex Committee on General Principles, for adoption and inclusion in the Codex Procedural Manual (see Appendix 1).

Proposed Revisions to the Codex Procedural Manual<sup>2</sup>

The CCFAC established an electronic Working Group led by Switzerland<sup>12</sup> to consider the relevant amendments to the Procedural Manual, including: i) Format for Codex commodity standards, section on food additives; ii) Relations between commodity committees and general committees, section on food additives and contaminants; and iii) Terms of reference of the Committee and to prepare a report with a first proposal of amendments to the Procedural Manual for circulation, comments and further consideration at the next session of the Committee. The proposed changes to the Procedural Manual should be consistent with the Preamble of the GSFA.

<sup>1</sup> ALINORM 06/29/12, paras. 57-60 and Appendix VI

<sup>2</sup> ALINORM 06/29/12, paras. 68-69

## Appendix 1

### Procedures for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives

(for inclusion in the Codex Procedural Manual)

#### *Scope*

The Codex General Standard for Food Additives (GSFA) is intended to include food additive provisions for standardised and non-standardised foods in the Codex Alimentarius.

The following text describes the data and information that should be submitted to CCFAC when requesting the Committee to initiate work to add or revise food additive provisions in the Codex General Standard for Food Additives. The decisions required to establish acceptance or rejection of new proposals are also elaborated.

Provisions for the use of processing aids (e.g., most enzyme preparations, clarifying and filtering aids, extraction solvents) are not included in the General Standard for Food Additives.

#### *Initiation of Work*

##### **Revision**

The food additive provisions of the GSFA may be revised by CCFAC after requests submitted by Codex Committees, Codex members, or the Codex Alimentarius Commission. Information to support amendment of the GSFA shall be provided by the proposing body. Supporting information provided to the CCFAC should include, as appropriate:

- Specifications for the food additive;
- A summary of the JECFA safety evaluation of the food additive;
- The food categories or sub-categories in which the additive is intended to be used;
- An indication of the technological need / justification for the additive, referencing one or more of the General Principles for the Use of Food Additives of the GSFA (Section 3);
- Maximum use levels for the food additive in the specified food categories:
  - For additives with a numerical ADI, a numerical maximum use level for each specified use although for certain cases, a level of GMP may be appropriate;
  - For additives with an ADI Not Specified or Not Limited, a recommendation to list the additive in Table 3 accompanied by additional proposals for inclusion in Tables 1 and 2 for use in the food categories listed in the Annex to Table 3, as appropriate;
  - For additives with an “acceptable” ADI, either a numerical maximum use level for the acceptable level of treatment of a food or a level of GMP, consistent with the JECFA evaluation.
- A justification of the maximum use levels from a technological point-of-view; and an indication, by means of the procedure indicated in Annex A of the GSFA or an exposure assessment, that this level meets the safety requirements enumerated in Section 3.1 of the GSFA.
- A reasoned statement that consumers will not be misled by the use of the additive.

The Codex Committee for Food Additives and Contaminants shall consider all amendments to the GSFA proposed by Codex Committees, Codex members, or the Codex Alimentarius Commission.

## Review

The food additive provisions for the GSFA shall be reviewed by CCFAC on a regular basis and revised as necessary in light of revisions of the risk assessment by JECFA or of changing technological need and justification for use.

- If JECFA changes an ADI to a Temporary ADI, the food additive provisions of the GSFA may remain unchanged until the ADI has been withdrawn or the full status has been restored by JECFA.
- If JECFA withdraws an ADI the food additive provisions of the GSFA shall be amended by removing all provision for the use of the additive.

The following additional guidance is provided regarding the information to be submitted:

- Identity of the food additive
  - Food additives shall have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives and either assigned a full numerical or non-numerical (“not specified” or “not limited”) Acceptable Daily Intake, or deemed to be acceptable for a particular use.
  - Food additives shall have been assigned an International Numbering System Number.
- Functional effect of the food additive
  - The functional class list used in the International Numbering System (CAC/GL 36) should be used.
- Proposed use of the food additive
  - The appropriate food categories from the food category system (Annex B of the General Standard for Food Additives) and maximum use levels should be specified.
  - With regard to the acceptable maximum use level:
    - A numerical use level should be provided for a food additive assigned a numerical Acceptable Daily Intake. However, in some cases, reporting the use level as good manufacturing practice (“GMP”) may be appropriate.
    - For a food additive assigned a non-numerical (“not specified” or “not limited”) Acceptable Daily Intake that is listed in Table 3 of the General Standard for Food Additives, a numerical or good manufacturing practice (“GMP”) use level should be provided for any request to list the additive in a food category in the Annex to Table 3.
    - For some food additives, the Acceptable Daily Intake has been reported on a specific basis (e.g., “as phosphorus” for phosphates; “as benzoic acid” for benzoates). For consistency, the maximum use level for these additives should be reported on the same basis as the Acceptable Daily Intake.
- Justification for the use and technological need of the food additive
  - Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives should be included.
- Safe use of the food additive
  - An intake assessment of the proposed use of the food additive, in accordance with Section 3.1 of the Preamble of the General Standard for Food Additives, should be included as appropriate.
- Justification that the use does not mislead the consumer
  - A reasoned statement that consumers will not be misled by the use of the additive should be provided.

***Does the food additive use meet the criteria of Section 3.2 of the Preamble of the General Standard for Food Additives?***

Section 3.2 of the Preamble of the General Standard for Food Additives establishes the criteria for justifying the use of a food additive. Adherence to these criteria is necessary for the inclusion of the food additive in the General Standard for Food Additives. If the use of the additive does not meet these criteria, it is not considered further and the work is discontinued. If the information provided to justify the use of the additive is inadequate for the Codex Commodity on Food Additives and Contaminants to reach a decision, further information on the use and technological justification and need for the food additive will be requested for consideration at the Committee's next Session. If this information is not provided by the next Session, work on the provision is discontinued.

***Is the food additive used in standardized food?***

The Codex Committee on Food Additives and Contaminants, asks the relevant Codex commodity committee to consider the functional classes of additives, additives, and their technological justification for the commodity and to refer back this information by the next available session.. In light of this information, the Codex Committee on Food Additives and Contaminants recommends appropriate conditions of use based on proposals of the commodity committee.

In certain cases, however, it may be appropriate for the Codex commodity committee to develop a list of food additives with associated functional classes and acceptable maximum use levels that would be forwarded to the Codex Committee on Food Additives and Contaminants for endorsement and, ultimately, incorporation into the General Standard for Food Additives. The development of such food additive lists should be consistent with the principles used in the development of the General Standard for Food Additives. However, the development of food additive lists in commodity standards should be restricted as much as possible. For example, an additive may be listed in a commodity standard if it is needed to achieve a technical effect that is not achievable by the use of other additives of the same functional class. Additives may also be listed in a commodity standard if there is a need, based on a safety assessment, to limit the use of the additive. Justification for such exceptions should be provided by the Codex commodity committees to the Codex Committee on Food Additives and Contaminants for consideration.

If the Codex commodity committee has been adjourned, the Codex Committee on Food Additives and Contaminants may revise the food additive provisions in commodity standards under the purview of the adjourned committee, as necessary.

The Codex Committee on Food Additives and Contaminants would consider any proposed revision in light of the principles of technological justification for the use of additives as indicated in Section 3.2 of the Preamble of the General Standard for Food Additives. These revisions, once adopted by the Commission, would be incorporated into the General Standard for Food Additives.

***Has a non-numerical ("Not Specified" or "Not Limited") Acceptable Daily Intake been assigned?***

Yes - Non-Numerical ("Not Specified" or "Not Limited") Acceptable Daily Intake:

Food additives assigned a non-numerical Acceptable Daily Intake are proposed for inclusion in Table 3 of the General Standard for Food Additives. Requests for the use of these additives in the food categories listed in the Annex to Table 3 are made by proposing provisions for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives and Contaminants according to the criteria described under "*Consideration of Conditions of Use in the Specific Food Categories,*" below.

No - Numerical Acceptable Daily Intake or Acceptable for Limited Use:

Food additives assigned a numerical Acceptable Daily Intake or evaluated to be acceptable for one or more particular uses are proposed for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives and Contaminants according to the criteria described under "*Consideration of Conditions of Use in the Specific Food Categories,*" below.

### *Consideration of Conditions of Use in the Specific Food Categories*

The Codex Committee on Food Additives and Contaminants identifies and recommends appropriate food categories and use levels for inclusion in Tables 1 and 2 of the General Standard for Food Additives. For this purpose, the Committee will consider the following general principles for the inclusion of a food additive provision in Tables 1 and 2 of the General Standard for Food Additives:

1. Food additives that share a numerical group Acceptable Daily Intake will be considered as a group without further restrictions on the use of individual additives in that group. However, in some cases, restrictions on the use of individual additives in that group could be appropriate (e.g., because of public health concerns).
2. Food additives that have multiple functional classes will be considered without further restrictions to their functional class.
3. In general, a numerical use level for a proposed use of a food additive in a food category is given preference over a use level reported as good manufacturing practice (“GMP”). However, exceptions, as noted under “*Initiation of Work*,” shall also be taken into account by the Codex Committee on Food Additives and Contaminants on a case-by-case basis.
4. When establishing the acceptable maximum level of use for an additive in a specified food category, the Codex Committee on Food Additives and Contaminants considers the technological justification for the proposed level and the exposure assessment in accordance with Sections 3.1 and 3.2 of the Preamble of the General Standard for Food Additives. If more than one maximum use level is proposed, and the Committee cannot reach consensus on the appropriate maximum use level, the delegations supporting and the delegations opposing the proposed maximum use level should provide additional justification for their proposed levels to address any specific concerns raised by the Committee, by the next available session. to the Codex Committee on Food Additives and Contaminants, for consideration in its next Session. Proposals lacking justification will no longer be considered, and the proposed level for which justification has been provided will be forwarded for adoption.
5. To resolve questions related to dietary exposure of food additives, the Codex Committee on Food Additives and Contaminants may request the Joint FAO/WHO Expert Committee on Food Additives to perform exposure assessments for the additives based on the acceptable maximum use levels under consideration by the Codex Committee on Food Additives and Contaminants.
6. Acceptable maximum use levels are established as described in the previous sections and the food additive provisions are entered in the General Standard for Food Additives. Each use level represents the highest acceptable maximum use level in the broadest food category for which the use is technologically justified. To the extent possible, the hierarchical structure of the food category system will be used to simplify the listing of the food additive provisions in Tables 1 and 2 of the General Standard of Food Additives. In this regard:
  - If the new use of a food additive is for a broader food category and at a maximum use level that is higher than or equal to those in the sub-categories of the broad food category that are already listed in the General Standard for Food Additives, then the new use in the broader food category supersedes the already-listed provisions. These provisions are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).

- If the new use of a food additive is for a broader food category and at a lower maximum use level than for the sub-categories of the broad food category that already exist in the General Standard for Food Additives, then the provisions listed in the General Standard for Food Additives are determined according to the hierarchy of the food category system. The highest maximum use level in each food sub-category, whether from an existing provision or from the new use in the broader food category, is entered into the General Standard for Food Additives. Any existing provisions that are superseded by the new use are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).
- If the new use of a food additive, together with the already-listed provisions in the General Standard for Food Additives, represents use in all of the sub-categories of a broader food category at the same maximum use level, then the use in the broader food category will be listed in the General Standard for Food Additives. The already-listed provisions in the sub-categories are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the provision in the broader food category at Step 8 (if adopted provision at Step 8).

**Diagram of procedure for consideration of the entry and review of food additives in the GSFA**

