codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 (a) **CX/FAC 05/37/7**
November 2004

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-seventh Session

The Hague, The Netherlands, 25-29 April 2005

PREAMBLE OF THE GENERAL STANDARD FOR FOOD ADDITIVES

PROGRESS REPORT OF THE WORKING GROUP ON THE WORKING PRINCIPLES OF THE GSFA

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 31 January 2005** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature and Food Quality, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl - ***preferably***), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org - ***preferably***).

BACKGROUND

1. At its 36th session, the Codex Committee on Food Additives and Contaminants (CCFAC) established an electronic Working Group led by China[1] to prepare a paper for discussion at its next session that outlines the working principles it had previously developed during its elaboration of the General Standard for Food Additives (GSFA).[2] The working group was charged with the following terms of reference :[3]

(a) Review the currently-used working principles applied by the Committee when developing the GSFA;

(b) Adapt these working principles with the objective to improve the work, taking into consideration that the development of the GSFA needs to respect the following criteria:

(i) The GSFA needs to be consistent with other standards adopted by the Codex Alimentarius Commission;

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1 Other members of the Working Group: Australia, Brazil, Canada, European Commission, France, India, Japan, Korea, Morocco, New Zealand, Sweden Switzerland, Thailand, United States, ELC, ICGMA,IDF, and IFU.

2 ALINORM 04/27/12, paras. 57-60

3 ALINORM 04/27/12, para. 59

(ii) The entries to the GSFA should be developed in a transparent manner;

(iii) The GSFA needs to be developed in a fair and consistent way; and,

(iv) The GSFA has been under development for more than 10 years, changes to the working principles should result in acceleration rather than leading to further delay.

(c) Describe the proposed amended working principles in a separate document that will accompany the GSFA. In a second step, the Working Group is asked to consider where these working principles would require the amendment of other documents adopted by the Commission;

(d) Analyze, as part of this work, the relationship between provisions of the GSFA and those of commodity standards and shall propose procedures that will assure consistency among different sections of the Codex Alimentarius that address the use of food additives in standardized foods; and,

(e) Present to the next Session of the Committee a progress report and possibly, depending on the progress made, questions in order to receive further comments.

2. Appendix I of this report contains a summary of the current working principles used by the Committee to elaborate the food additive provisions in the GSFA. Appendix II of this report contains a "decision-tree" outlining the process the Committee is currently using to elaborate the food additive provisions in the GSFA.

3. Appendices I and II address the working group's charge described in paragraph 1(a) and facilitates the working group's discussion of its charges described in paragraph 1(b-c).

4. Appendix III of this report contains a summary analysis of the inconsistencies among the GSFA Preamble, the Codex Procedural Manual, and the Codex General Principles for the Use of Food Additives (CAC/MISC 1-1972). The information contained in Appendix III is responsive to the working group's charge contained in paragraph 1(d).

5. The Committee also noted that the Codex Alimentarius Commission (26th session) had approved as new work the revision of the Preamble of the Codex General Standard for Food Additives (GSFA).[4] In partial response to the above terms of reference and noting that the Committee, at its 36th session, had also considered some recommendations for revision of the Preamble that were presented in working document CX/FAC 04/36/6,[5] the Working Group used this document and comments received[6] as the basis for a proposed revised Preamble (see Appendix IV) for comment and discussion at the 37th session of the Committee.

COMPARISON OF CODEX PRINCIPLES AND PROCEDURES FOR FOOD ADDITIVE USAGE (APPENDIX III)

6. Appendix III of this report compares the existing principles and procedures for food additive usage represented in the General Principles for Food Additives[7], the Codex Procedural Manual[8] and the Preamble to the General Standard for Food Additives.[9]

7. The Row numbers listed in the following paragraphs refer to the numbers indicated in the first column in the comparative table. Where the evaluation has found significant differences, these are listed and discussed below.

4 ALINORM 04/27/12, para. 53
5 ALINORM 04/27/12, para. 54
6 CX/FAC 04/36/6-Add.1
7 General Principles for the Use of Food Additives, CAC/MISC 1-1972
8 Codex Alimentarius Procedural Manual, 13th Edition, Relations between Commodity Committees and General Committees, pp 95-96, 2003
9 General Standard for Food Additives, CODEX STAN 192-1995, Rev. 4 – 2003, Preamble, pp 1-5

8. Row 11: Whereas the General Principles limit the use of a food additive to *specific foods* for a *specific purpose* and *specific condition* the Preamble refers to a hierarchical food category system. This means that when the use of an additive is permitted in a general category, it is automatically permitted in all its sub-categories (unless otherwise stated). In other words the use is rather *unspecific*.

9. Row 12: The General Principles specify the use level as the *lowest level* necessary to achieve the desired effect. Whilst the Preamble covers food additives, their *maximum levels*, and their actual use level which is limited to the lowest possible level necessary to achieve its intended technical effect.

10. Row 14: The Procedural Manual specifies that commodity committees should prepare a section on additives in each draft commodity standard and that these provisions should be referred to the CCFAC for endorsement. However the Preamble indicates that the food additive provisions of the commodity standards are superseded by the provisions set in the GFSA. The Procedural Manual establishes that the expertise for additive recommendations within commodity standards lies with the commodity committees, while the CCFAC has overall expertise in risk management of additives in standardised and non-standardised foods from a health and safety point-of view.

11. Row 16: The Procedural Manual indicates that the provisions will require endorsement by the CCFAC based on the technological justification submitted by the commodity committees. However, the Preamble indicates that provisions may be initiated by Codex committees, Member States or the Commission. In addition, even though not stated, NGOs have also been recommending changes and the inclusion of additional additive uses in the GSFA and during the elaboration of Codex commodity standards.

12. Row 19: This paragraph states that committees should follow the General Principles as well as the Preamble. However, in the next sentence it remains unclear what “above recommendations” means. Is it the recommendation to follow the rules in the General Principles and Preamble or the rules listed in the preceeding paragraphs (above) of the Procedural Manual? In addition, it would be difficult to follow the recommendations in both the General Principles and the Preamble because they differ in various aspects.

13. Row 20: Similar to Row 16 the Procedural Manual states that commodity committees shall prepare the proposals for the use of additives, whereas the Preamble specifies that CCFAC shall consider all proposed amendments from the Codex Alimentarius Commission, Codex committees and Codex Member States.

PROPOSED REVISIONS TO THE PREAMBLE OF THE GSFA (APPENDIX IV)

14. The following proposed revisions to the Preamble can be viewed as significant:

a) An explicit statement in Section 1.2 that the use of additives in standardized foods is subject to the conditions of use established by the commodity standards and by the GSFA.

b) A statement in Section 1.2 that commodity committees have the responsibility to establish the technological need for the use of additives in foods subject to a commodity standard.

c) Clarification of the description of the GSFA (Section 6).

d) A new addition to Section 6 that addresses the CCFAC’s agreement on the principles for assigning maximum levels for the use of food additives.[10]

e) A restriction on application of the carry-over principle for certain foods (Section 4)

f) Removal of the word “permitted” as a modifier to “food additive”, when modifying “maximum level”, or “maximum use level”.

g) A new definition in Section 2 for “Maximum level of use” in consideration of point (f).

[10] ALINORM 03/12A, para. 44

15. The change elaborated in point (f) and embodied in the new definition for "Maximum level of use" emphasizes: 1) the importance of distinguishing between a GSFA maximum use level and an optimum, recommended, or typical use level; and 2) the role that Codex standards play in providing sovereign states with guidance for crafting and implementing their national legislation, laws and regulations.

16. Points (f) and (g) also emphasize that the food additive provisions in the GSFA give recommendations for levels of use that should not be exceeded in foods traded internationally and that the responsibility of Codex lies in elaborating standards and codes of practice that provide guidance for Member Countries to apply when establishing their national food safety measures. Moreover, Codex is not responsible for "approving" or "permitting" practices and procedures for food production.

17. The proposed revised Preamble is presented in Appendix IV. The rationales for the proposed revisions are presented using a stepwise process through the entire Preamble that shows all proposed additions (**bold font**) and deletions (~~strikethrough~~). In certain instances, unchanged text is simply denoted by "……." Note that some of the footnotes accompanying the text also contain proposed revisions.

18. **Section 1.1 -** The term "permitted" has been deleted and the criteria for inclusion of an additive in the GSFA have been made explicit and reflect the criteria that the CCFAC has been using. Additionally, as some additives in the GSFA are not assigned an ADI, but have been deemed "acceptable" for limited use (e.g., shellac, nitrous oxide) by the JECFA, language has been added to take such designations into account and bring the section in line with Section 3.1(b).

19. As agreed at the 36th CCFAC[11] and adopted by the 27th CAC, a new footnote is included that references the JECFA website to provide access to the most up-to-date information on ADIs. The footnote also indicates that the JECFA Secretariat is developing an index of the additives in the GSFA that includes the year of the most current evaluation, and the INS number of each additive:

> **1.1 ~~Permitted~~ Food Additives Included in this Standard**
>
> Only the food additives listed herein are ~~permitted~~ **recognized as suitable** for use in foods in conformance with the provisions of this Standard.[12] Only food additives ~~which~~ **that** have been **assigned a full Acceptable Daily Intake (ADI) or given an equivalent safety assessment** ~~evaluated~~ by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)[13] **and an International Numbering System (INS) designation by Codex** ~~and found acceptable for use in foods~~ are included in this Standard. **The use of additives in conformance with this standard is considered to be technologically justified.**

20. **Section 1.2** – This section has been modified to emphasize and clarify the roles of the Codex commodity committees in establishing the food additive provisions of the GSFA (see paragraphs. 14a and 14b):

> **1.2 Foods in Which Additives May Be Used**

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11 ALINORM 04/27/12, para. 56 and Appendix IV

12 Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is substantially complete.

13 An index of food additives with their current ADI status, the year of their most recent JECFA evaluation, their assigned INS numbers, etc., are available at the Joint Secretariat's web pages at http://www.fao.org/es/ESN/jecfa/index_en.stm for FAO and http://www.who.int/pcs/jecfa/jecfa.htm for WHO. [under development]

This Standard sets forth the conditions under which ~~permitted~~ food additives may be used in all foods, whether or not they have previously been standardized by Codex. **The use of additives in foods standardized by Codex is subject to the conditions of use established by the Codex commodity standards and this standard.** The food additive provisions of Codex commodity standards shall be included in and superseded by the provisions of this Standard. ~~These provisions also comply with the other requirements of the Preamble.~~ **Codex commodity committees have the responsibility and expertise to appraise and justify the technological need for the use of additives in foods subject to a commodity standard. The information given by the commodity committees may also be taken into account by the Codex Committee on Food Additives and Contaminants when considering food additive provisions in similar non-standardized foods. When a food is not covered by a commodity committee, the Codex Committee on Food Additives and Contaminants will appraise the technological need.**

21. **Section 1.3** – Minor change.

1.3 Foods in Which Additives May Not Be Used

Food categories or individual food items ~~where~~ **in which** the use of food additives **is** ~~are~~ not allowed or **is** ~~are~~ restricted are defined by this Standard.

22. **Section 1.4** –"Permitted" has been deleted. Also, noting that the CCFAC is not encouraging submission of food consumption data to it, but, rather, evaluation of such data by member countries or other bodies for use in establishing maximum levels of use, a word substitution was made:

1.4 ~~The Permitted~~ Maximum Levels of Use for Food Additives

The primary objective of establishing ~~permitted~~ **maximum** levels of use ~~of~~ for food additives in various food groups is to ensure that the intake of **an** additive **from all its uses** does not exceed ~~the~~ **its** ~~acceptable daily intake~~ **ADI**.

The food additives covered by this ~~s~~**S**tandard and their maximum levels of use are based……an appropriate method ~~which would verify~~ **for verifying** the compatibility of a proposed maximum level with the ADI.

~~The Danish budget method~~ **Annex A of this Standard** may be used as a first step in this regard.[~~14~~] The ~~submission~~ **evaluation** of actual food consumption data is also encouraged.

23. **Section 2** – The primary proposed change in this section is addition of a definition for "Maximum level of use". Additionally, it seemed desirable to elaborate on the meaning of the phrase "without appreciable health risk," which appears in the definition for "Acceptable Daily Intake (ADI)" in Section 2(b). This elaboration is added to the existing footnote. In 2(b) the reference to the "standard man = 60 kg" has been removed because the ADI is expressed on a per kg basis, making it independent of bodyweight. In the definition for the ADI "Not specified," minor edits have been made. The "discussion" parts of both definitions (c) and (d) have been separated, for clarity, from the basic definitions. Thus, Section 2 becomes:

a) ***Food additive*** means ……qualities.[15]

b) ***Acceptable Daily Intake (ADI)*** is an estimate by JECFA …….without appreciable health risk ~~(standard man = 60 kg)~~.[16]

[~~14~~] "~~Consensus Document on the Danish Budget Method", Nordic Working Group on Food Toxicology and Risks Evaluation, Report No. 4/90.~~

[15] Codex Alimentarius **Procedural Manual**~~, Second Edition (Revised 1995) Volume 1A (General Requirements), p. 11~~.

[16] Principles for the Safety Assessment of Food Additives and Contaminants in Food, World Health Organization, (WHO Environmental Health Criteria, No. 70), P. 111 (1987). **For the purposes of this Standard, the phrase "without appreciable health risk" means that there is a reasonable certainty of no harm to consumers if an additive is used at levels that do not exceed those in this Standard. The provisions of this Standard do not sanction the use of an additive in a manner that would adversely affect consumer health.**

c) ***Acceptable Daily Intake "Not Specified" (NS)***[17] is a term applicable….. represent a hazard to health.

For **the above** ~~that~~ reason, and for reasons stated in individual JECFA evaluations, establishment of an acceptable daily intake expressed in numerical form is not deemed necessary by JECFA. An additive meeting **the above** ~~this~~ criterion must be used within the bounds of good manufacturing practice as defined in ~~subparagraph~~ **section** 3.3 below.

d) ***Maximum level of use*** **of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food.**

The maximum level will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.

24. **Section 3** – A proposed new paragraph 3.1 (c) is introduced to state explicitly a basic principle for the use of additives. Other notable proposals include an update of the footnote on intake assessment, an extension (Section 3.4) of the meaning of "food grade quality", and an expansion of the footnote in Section 3.4 to provide information for accessing Codex Advisory Specifications on the internet:

3. GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES[18]

The use of food additives in conformance with this Standard requires adherence to all the principles set forth in Sections 3.1 – 3.4.

3.1 Food Additive Safety {note: this is a new proposed title}

a) Only those food additives shall be endorsed and included in this Standard ~~which~~ **that**, so far as can be judged on the evidence presently available from JECFA, present no **appreciable health risk to consumers** ~~risk to the health of the consumer~~ at the levels of use proposed.

b) The inclusion of a food additive in this Standard shall have taken into account any ~~Acceptable Daily Intake~~ **ADI**, or equivalent **safety** assessment, established for the additive by JECFA and its probable daily intake[19] from all **food** sources. Where the food additive is to be used in foods eaten by special groups of consumers **(e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets),** account shall be taken of the probable daily intake of the food-additive by **those** consumers. ~~in those groups.~~

c) **The quantity of an additive added to food is at or below the maximum level and is the lowest level necessary to achieve the intended technical effect. The maximum level may be based on the intake assessments of Codex member countries or upon a request by the CCFAC to JECFA for an independent evaluation of national intake assessments.**

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17 For purposes of this Standard, the phrase acceptable daily intake (ADI) "not limited" (NL) has the same meaning as ADI "not specified". The phrase "acceptable ADI" refers to an ADI which is more appropriately limited by the level of treatment of the food, rather than on a mg additive per kg body weight per day basis (see, Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives ~~(JECFA), FAO/WHO, ILSI Press, 1999, Part 1, p.3)~~ **.at http://jecfa.ilsi.org.**

18 General Principles for the Use of Food Additives were originally adopted by the Ninth Session of the Codex Alimentarius as a Codex Advisory Text (para. 295, ALINORM 72/35) ~~and were reprinted in the Second Edition of the Codex Alimentarius, Vol. 1A, (General Requirements) pp. 45-47 (Revised 1995).~~ Pertinent portions of the Text ~~have now been~~ **are** incorporated as an integral part of this Standard, suitable modifications having been made as necessary with respect to the present context.

19 ~~"Guidelines for Simple Evaluation of Food Additive Intake", CAC/VOL. XIV Ed. 1, Supplement 2 (1989), gives procedures for calculating the theoretical maximum daily intake (TMDI) and the estimated daily intake (EDI) of food additives; other appropriate procedures may be used to calculate the TMDI and EDI.~~ **Codex member countries may provide the Codex Committee on Food Additives and Contaminants (CCFAC) with intake information that may be used by the CCFAC in establishing maximum levels of use. Additionally, the JECFA, at the request of the CCFAC, will evaluate intakes of additives based on intake assessments submitted by Codex member countries responding to a call for data. The CCFAC will consider the JECFA evaluations when establishing the maximum use levels for additives.**

3.2 Justification for the Use of Additives {note: this is a new proposed title}

The use of food additives is justified only when such use has an advantage, does not present **an appreciable health risk to consumers** ~~a hazard to health of and~~**,** does not mislead the consumer, and serves one or more of the technological functions set out by Codex and **the** needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means ~~which~~ **that** are economically and technologically practicable:

a) to preserve the nutritional quality ……diet;

b) to provide necessary ingredients……..special dietary needs;

c) to enhance the keeping quality……..deceive the consumer;

d) to provide aids in the manufacture, processing, ….. practices ~~of~~ **or** techniques during the course of any of these activities.

3.3 Good Manufacturing Practice (GMP)[20]

All food additives subject to the provisions of this Standard shall be used under conditions of good manufacturing practice, which include the following:

a) the quantity …….to accomplish its desired effect;

b) the quantity …….reduced to the extent reasonably possible; and,

c) the additive is **of appropriate food grade quality and is** prepared and handled in the same way as a food ingredient.

3.4 Specifications for the Identity and Purity of Food Additives

Food additives ……. should be of appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity….. Codex Alimentarius Commission[21] or, ……developed by responsible national or international bodies. In terms of safety, food grade quality is achieved by ~~compliance with the~~ **conformance of additives to their** specifications as a whole ~~and~~ **(**not merely with individual criteria**) and through their production, storage, transport, and handling in accordance with GMP.**

25. **Section 4** – An additional subsection (4.3) is proposed to list foods for which the carry-over principle would not apply. Specifically, foods for infants are noted (e.g., infant formulae, follow-up formulae) as these foods may constitute most, if not all, the nutrition to an infant. The exclusion would make clear the Committee's intent (if agreed) that additives carried over from ingredients used for these special foods should be explicitly authorized. Minor changes are also proposed relating to deleting "permitted." Thus:

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20 For additional information, see the Codex Alimentarius Commission Procedural Manual~~, Tenth Edition (1997), p. 78~~.

21 ~~Food additive specifications endorsed by the Codex Alimentarius Commission are included in the JECFA "Compendium of Food Additive Specifications," Volumes 1 and 2 (1992) and in addenda thereto, published by FAO.~~ **An index (CAC/MISC 6 – 2001) of all specifications adopted by the Codex Alimentarius Commission, as well as the year of adoption, is available at the Codex website (http://www.codexalimentarius.net/web/Standard_list.do?lang=en). These specifications, prepared by the JECFA, are also being published in the FAO Food and Nutrition Paper series as the "Compendium of Food Additive Specifications," which consists of two volumes published in 1992 and a subsequent series of addenda. The specifications are also available at the JECFA website (http://www.fao.org/es/esn/Jecfa/database/cover.htm). However, neither this website nor the addenda to the Compendium contain information that shows which specifications have been adopted by Codex.**

4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS[22]

4.1 Compliance with the Carry-over Principle

Other than by direct addition, an additive may be present in a food as a result of carry-over from a food ingredient, subject to the following conditions:

a) The additive is ~~permitted~~ **acceptable** …… this ~~General~~ Standard;

b) The amount of the additive ……not exceed the maximum ~~amount~~ **level specified in this Standard** ~~so permitted~~.

c) The food……manufacturing practice.

4.2 Ingredients and Raw Materials as Carriers for Additives[23]

An additive is ~~permitted~~ **may be used** in a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a ~~food which~~ **food that** is in conformity with the provisions of ~~the~~ **this** ~~s~~**S**tandard.

4.3 Foods for Which the Carry-over Principle Does Not Apply

a) Infant formulae, follow-up formulae, and formulae for special medical purposes for infants (Food Category 13.1).

b) Complementary foods for infants and young children (Food Category 13.2).

26. **Section 5** – Changes are proposed relating to removal of "permitted" and the footnote referencing the food category system (Annex B) is updated. Additional clarifications in the first paragraph and in sub-paragraph (c) have also been made. Thus:

5. FOOD CATEGORY SYSTEM[24]

The food category system is a tool for ~~the allocation of~~ **organizing** food additive uses ~~authorized by~~ **in** this Standard. The food category system applies to all foodstuffs**.** ~~including those in which no additives are permitted~~.

The food **category** descriptors are not to be legal product designations nor are they intended for labelling purposes.

The food category system is based on the following principles:

a) The food category system is hierarchical, meaning that when ~~the use of~~ an additive is ~~permitted~~ **recognized for use** in a general category, it is ~~automatically permitted~~ **recognized for use** in all its sub-categories, unless otherwise stated. Similarly, when an additive is ~~permitted~~ **recognized for use** in a sub-category, its use is ~~also allowed~~ **recognized** in any further sub-categories ~~and in descriptors~~ or individual foodstuffs mentioned in a sub-category.

b) The food category system is based on product descriptors of foodstuffs as marketed, unless otherwise stated.

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22 The principle relating to the carry-over of food additives into foods (the "Carry-Over Principle") addresses the presence of additives in food as a result of the use of raw materials or other ingredients in which these additives are used. The Codex Alimentarius Commission at its 17th Session (1987) adopted a revised statement of the principle as a Codex Advisory Text. ~~The Text is printed in its entirety in Codex Alimentarius, Second Edition, Vol. 1A (General Requirements), pp. 94- 95, 1992~~. The Carry-Over Principle applies to all foods covered by Codex standards, unless otherwise specified in such standards.

23 See ALINORM 97/12, para. 44.

24 **Annex B to this Standard.** ~~Each Codex Commodity Standard has been initially assigned to one of the~~ **a** ~~food categories or sub-categories of the food category originally based on the system developed by the Confédération des Industries Agro-Alimentaires de la CEE (CIAA). It is expected that the food category system for the Standard (CL 1996/14-FAC) will form the basis of a new food classification scheme that will be eventually proposed for adoption by the CAC. Codex Standard Numbers (CXSNs), together with the corresponding names of the Codex Commodity Standards and the food categories and sub-categories to which the CXSNs have been classified, are listed in ANNEX B.~~

c) The food category system takes into consideration the carry-over principle. ……(e.g., prepared meals, **such as pizza,** because they may contain, *pro rata*, all the additives ~~allowed~~ **endorsed for use** in their components), ~~except when~~ unless the compound foodstuff needs an additive ~~which~~ that is not ~~authorized~~ **endorsed for use** in any of its components.

The food category system is ……constructing this Standard.

27. **Section 6** – A change in title from "Format of the Standard" to "Description of the Standard" is proposed and a listing of all parts of the Standard is given, which includes a new sub-section delineating the three Annexes associated with the Standard. Existing language has been updated for clarity:

6. ~~FORMAT~~ DESCRIPTION OF THE STANDARD

This Standard consists of three main components:

a) Preamble

b) Annexes

i. Annex A is a guideline for considering maximum use levels for additives with numerical JECFA ADIs.

ii. Annex B is a listing of the Food Category System used to develop and organize Tables 1, 2, and 3 of the Standard. Descriptors for each food category and sub-category are also provided.

iii. Annex C is a cross-reference of the Food Category System and Codex commodity standards.

c) Food Additive Provisions

~~The food additives listed herein have been grouped into the 23 major functional classes of the Codex International Numbering System (INS) for Food Additives.[25]~~

i. Table 1 ~~of this Standard~~ specifies, for each food additive or food additive group (in alphabetical order) **with a numerical JECFA ADI**, the **food categories (or** foods**)** in which the additive is ~~acceptable~~ **recognized** for use, ~~together with~~ the ~~acceptable~~ maximum use levels **for each food or food category, and its technological function**. Table 1 also includes the uses of those additives with non-numerical ADIs for which a maximum use level is specified.

ii. Table 2 ~~of this Standard~~ contains the same information as Table 1, but the information is arranged by food category number.

iii. Table 3 ~~of this Standard~~ lists additives …….preamble. The Annex to Table 3 lists ……...

Unless otherwise specified, maximum **use** levels for ~~food~~ additives **in Tables 1 and 2** are set on the final product as consumed.

Tables 1, 2, and 3 do not include references to the use of substances as processing aids.[26]

~~[25] Although the General Standard as currently drafted covers only antioxidants and preservatives, the complete Standard will eventually cover the uses of food additives in all 23 INS functional classes; see Codex Alimentarius Vol. 1A, Second Edition (Revised 1995), Section 5.2, pp. 57-92.~~

[26] **Processing Aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product~~.~~: Codex Alimentarius Commission, Procedural Manual~~.

28. **Section** 7 – The points in section 7.2 were increased from four to seven to include a statement, consistent with Section 3.2, that consumers will not be misled by use of an additive and to improve the guidance with respect to information on technological justification/need and proposed maximum use levels. The final statement of 7.2 was extended to make it clear that CCFAC must consider all proposals by the specified initiating bodies. Other changes are simply editorial:

7. REVIEW AND REVISION OF THE STANDARD

7.1 Review ~~of the Standard~~

The food additive provisions….. revisions of **the** ~~Acceptable Daily Intakes~~ **ADIs** by JECFA or of changing technological need and justification for use.

7.2 Revision ~~of the Standard~~

The food additive provisions …….revisions ~~of this Standard~~ may be initiated by recommendations ~~by~~ **of** Codex Committees, Codex member ~~States~~ **countries** ……. proposing body. Supporting information ~~that shall be~~ provided to the ~~Codex Committee on Food Additives and Contaminants~~ **CCFAC** ~~may~~ **should** include, as appropriate:

- Specifications for the food additive;
- **A summary of the JECFA safety evaluation of the food additive;**
- ~~Intended food category or sub-category;, and use level for the additive;~~ **The food categories or sub-categories in which the additive is intended to be used;**
- ~~Summary of JECFA safety evaluation of the food additive; and~~
- ~~Technological justification and need for the additive.;~~ **An indication of the technological need / justification for the additive, referencing one or more of the General Principles for the Use of Food Additives enumerated in Section 3.2 of this Standard;**
- **Maximum use levels for the food additive in the specified food categories:**
  - **For additives with a <u>numerical</u> ADI, a numerical maximum level for each specified use;**
  - **For additives with an ADI <u>Not Specified</u>, 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;**
- **A justification of the maximum use levels from a technological point-of-view; and an indication, by means of an exposure assessment, that this level meets the safety requirements enumerated in Section 3.1 of this Standard.**
- **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 ~~proposed~~ amendments to this Standard **proposed by Codex Committees, Codex Member Countries, or the Codex Alimentarius Commission**.

APPENDIX I

CURRENT WORKING PRINCIPLES FOR ELABORATION OF THE GSFA

I. SCOPE OF THE STANDARD:

The GSFA is intended to include food additive provisions for standardized and non-standardized foods in the Codex Alimentarius system. It is intended to ultimately be the source of all information on food additive uses in the Codex system. While processing aids are a subset of food additives and many food additives may be used as processing aids, the GSFA does not include provisions for the use of processing aids.

II. DEVELOPMENT OF THE STANDARD

Food Category System

The GSFA's food category system is intended to cover all foods in international trade. It applies to all foods, including those in which additives are not needed. Importantly, the food category titles are neither legal product designations, nor are they intended for labeling purposes.

The food category system is organized into 16 major categories that are generally based on major food commodity groups (e.g., dairy, fats and oils, fruits and vegetables, meat, grain, fish). These major categories are subdivided to reflect similar processing (e.g., frozen, fresh, dried, etc) or to reflect similarities in food consumption patterns (e.g., infant formula, condiments, beverages).

When interpreting the food additive provisions in the GSFA, it is important to recognize that the food category system is hierarchical. This means that provisions listed in a category apply to foods subject to that category and all subcategories, as well. Also, the categories and the subcategories are mutually exclusive.

The food category system forms the framework upon which the GSFA food additive provisions have been organized. As such the category system has served to simplify the reporting of food additive uses for assembling and constructing this standard.

III. ASSEMBLING THE DRAFT FOOD ADDITIVE PROVISIONS IN THE GSFA

The CCFAC has taken the following approach toward assembling the additive provisions in the GSFA. Only additives assigned a full ADI by the JECFA and that have an INS Number were considered by CCFAC in assembling the GSFA. Additive use information was collected from the following sources: Codex Member Countries, Codex commodity standards, and recognized international non-governmental organizations. The Committee systematically collected and assembled additive use information from these sources over several years using the INS functional classes. In some instances, the sources proposed food additive uses associated with food additive functional classes (e.g., emulsifier, acidity regulator) for additives that are not recognized in the INS or have not been evaluated by JECFA. All additive use information was included in Table 1 of the GSFA.

Processing aids, (e.g., enzymes preparations, clarifying and filtering agents, and extraction solvents) are not part of the GSFA. CCFAC has agreed that provisions for processing aids would continue to be included in Codex commodity standards and that the Codex Inventory of Processing Aids would be updated until CCFAC develops an alternative approach for addressing processing aids within the Codex system.

A. Technological Need

Section 3.2 of the Preamble of the GSFA establishes the following bases to justify the use of a food additive. Adherence to these conditions is necessary for the use of an additive to conform to the GSFA.

> The use of food additives is justified only when such use has an advantage, does not present a hazard to health of and does not mislead the consumer, and serves one or more of the technological functions set out by Codex and needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means which are economically and technologically practicable:

a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;

b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;

d) to provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices of techniques during the course of any of these activities.

When considering whether the use of an additive is technologically needed, the CCFAC has agreed that whenever possible, technological need should be addressed through consideration of additive classes, instead of an additive-by-additive approach.

Finally, the CCFAC has taken the approach that approval of a food additive by a Codex Member Country should, in the first instance, be taken as evidence of technological need. Furthermore, in deciding whether to include a provision in the GSFA, the committee may need to consider whether a use may be necessary only for a specific food or geographic region.

B. Combining and Simplifying the Additive Use Information

1. Additives Assigned ADIs "Not Specified"

The CCFAC placed additives assigned an ADI "not specified" by JECFA in Table 3 of the GSFA. Provisions for the use of these additives in the food categories listed in the Annex to Table 3 are included in Tables 1 and 2.

2. Additives Assigned Numerical ADIs

The CCFAC placed provisions for additives assigned a numerical ADI by JECFA or judged by JECFA to be acceptable for a particular use (e.g., flour treatment agent) in Tables 1 and 2.

3. Simplification of the Food Additive Provisions in Tables 1 and 2

The CCFAC has taken the following approach to simplify the food additive provisions in Tables 1 and 2.

- Provisions for additives assigned a group ADI by JECFA (e.g., phosphates, sulfites, benzoates) were combined under one listing in Tables 1 and 2.
- Proposed numeric maximum levels were given preference over GMP-only limitations.
- The highest reported maximum use level in the broadest reported food category was used as the starting point for discussions by the Committee.

4. Quality Control Working Group

The Committee established an *ad hoc* electronic working group to verify the accuracy of the additive provisions reported by the various country and NGO sources.

IV. PRIORITIZATION OF ADDITIVES

To manage its work on the GSFA, the CCFAC agreed to a priority-ranking of additives listed in Tables 1 and 2, with the understanding that this ranking would be used by the committee to optimize and focus its discussions of the pending additive provisions in the GSFA.

V. ESTABLISHING MAXIMUM LEVELS

The Committee has identified two criteria for establishing food additive maximum levels in the GSFA: 1) Exposure assessment and 2) technological justification. The Committee has established the following approaches to address each of these criteria.

A. General Principles for the Use of Additives

Section 3.3 of the Preamble of the GSFA establishes conditions that apply to all maximum use levels in the GSFA. These are:

> All food additives subject to the provisions of this Standard shall be used under conditions of good manufacturing practice, which include the following:
>
> a) the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;
>
> b) 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 technical effect in the food itself, is reduced to the extent reasonably possible; and,
>
> c) the additive is prepared and handled in the same way as a food ingredient.

B. Justification of the Level

The CCFAC has agreed[1] to the following procedure to resolve questions raised by Codex Member Countries regarding whether the proposed maximum level of use for a specific additive in a specific food category is justified.

- Establish that at least two Codex Member Countries permit the use of the additive up to the maximum level proposed in Tables 1 and 2 in foods representative of the category. This establishes that trade may occur in the food containing the additive.
- Establish whether the maximum level proposed is limited to an obscure or unrepresentative food. If so, consideration may be given to recognizing that food and the level of additive use as a specific entry in the GSFA, and identifying a more representative level for the category as a whole.
- Use “square brackets” as appropriate, where Codex Member Countries continue to express concern about the proposed maximum levels, and;
- Circulate the revised draft Tables 1 and 2 for comments:
  - If a Member Country considers the proposed level of use too high, data should be presented to demonstrate that the use level presents a risk to public health, may lead to consumer deception about the nature of the food, or is otherwise technologically unnecessary, and
  - If a Member Country wishes to support a draft maximum use level which has been identified as being of concern by other Codex Members Countries, data should be presented to demonstrate that the product could not be made to a satisfactory quality using a lower level of additive or alternative additives that are listed in the GSFA.

C. Consideration of JECFA ADIs

Section 3.1(a) of the Preamble of the GSFA states that: “Only those food additives shall be endorsed and included in this Standard which, so far as can be judged on the evidence presently available from JECFA, present no risk to the health of the consumer at the levels of use proposed.”

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[1] See ALINORM 99/12, para 47

In general, the Committee has agreed to assign a limit of "Good Manufacturing Practices" (GMP) for additives assigned an ADI "not specified" by JECFA. For example, Table 3 of the GSFA lists food additives assigned an ADI "not specified" by JECFA that may be used in foods generally under conditions of GMP except for the use in food categories listed in the Annex to Table 3. As noted above, Tables 1 and 2 contain provisions for the use of some of the Table 3 food additives in the food categories listed in the Annex to Table 3. It should be noted that some of these provisions in Tables 1 and 2 have numeric maximum use levels.

In cases where JECFA has determined that specific uses of an additive are "acceptable" under current conditions of use, the CCFAC has agreed to numeric and non-numeric maximum levels in the GSFA, depending on whether JECFA has determined a numerical limit on the acceptable use. For example, JECFA determined that the use of chlorine is "acceptable" as a flour treatment agent at a level not to exceed 2.5 g/kg flour. Subsequently, the CCFAC endorsed the use of chlorine as a flour treatment agent in food category 6.2 (flours and starches) with a maximum treatment limit of 2500 mg/kg. In contrast, where JECFA has determined that the use of an additive is Aacceptable@ and has not specified a limitation on its level of use, the CCFAC has endorsed its use with a maximum limit of GMP (e.g., shellac).

In cases where JECFA has assigned a numeric ADI, the CCFAC has agreed in general that it is preferable to assign a numeric maximum use level.

D. Intake Assessment

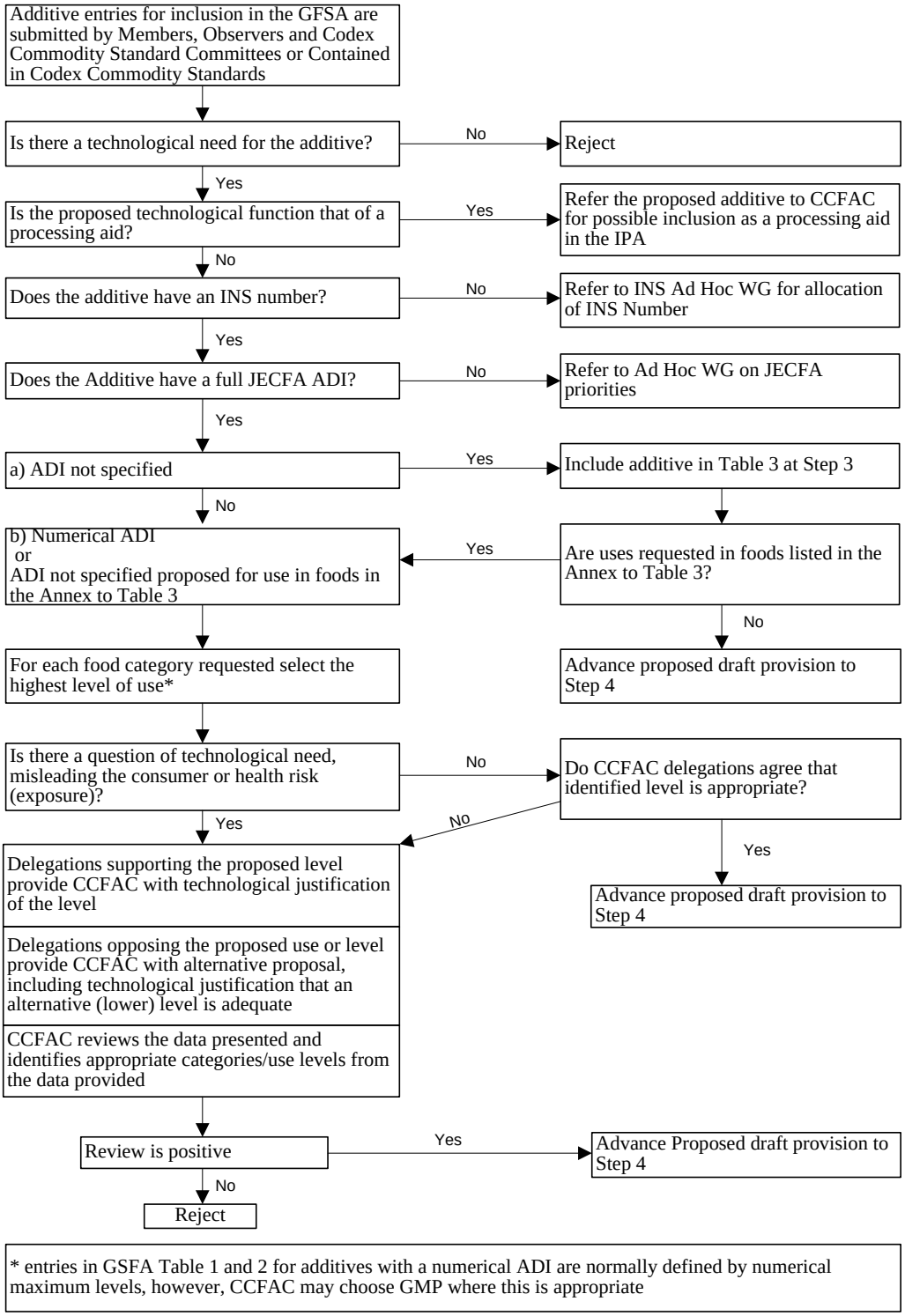
Section 3.1(b) of the Preamble of the GSFA states that "The inclusion of a food additive in this Standard shall have taken into account any Acceptable Daily Intake, or equivalent assessment, established for the additive and its probable daily intake from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account shall be taken of the probable daily intake of the food additive by consumers in those groups."

For additives in the draft GSFA with numerical ADIs, the CCFAC has established the following procedure for determining whether the maximum levels for a food additive may lead to consumer intakes that exceed the ADI:

- Application of the Budget Method described in Annex A of the Preamble to the GSFA is the first step. If the Annex A screen does not identify any safety concern, the CCFAC will forward the provisions for adoption at Step 8 (examples include: caramel color class III, caramel color class IV, fast green FCF, ferrous gluconate).
- At the request of Member Countries, the CCFAC will refer the draft provisions for specific additives to the JECFA for intake assessment to determine whether, based on national intake data, the JECFA ADI is likely to be exceeded and to identify which draft provisions contribute significantly to dietary exposure. The CCFAC will then review JECFA's recommendations, based on their intake assessment, to determine whether to revise the provisions in the draft GSFA (examples include: BHA, BHT, Benzoates, TBHQ, Sulfites (51st JECFA, 1998), and Annatto Extract, Canthaxanthin, Erythrosine, Iron Oxides (53rd JECFA, 1999)

APPENDIX II

DIAGRAM OF CURRENTLY USED PROCEDURE FOR ADDITIVES PROPOSED FOR ENTRY INTO THE GFSA



APPENDIX III

COMPARISON OF GSFA PREAMBLE WITH THE CODEX PROCEDURAL MANUAL AND THE GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES, (AC/MISC 1-1972) [1]

Table para	General Principles for the use of Food Additives[2]		Codex Procedural Manual[3]		Preamble to the General Standard for Food Additives[4]		Evaluation
1	Para 1	Additives subjected to appropriate toxicological testing and evaluation.			Para 1.1	Only additives listed are permitted for use in foods in conformance with the provisions of this standard. Only additives evaluated by JECFA and found acceptable for use in foods are included.	Same
2	2	No hazard to the health of the consumer at the level of use proposed.			3.1.a	Present no risk to the health of the consumer at the levels of use proposed	Same
3	3	Additives should be kept under continuous observation and should be re-evaluated when necessary.			7.1	Review of the Standard: done on a regular basis in light of revisions of ADI, or changing technological need and justification for use	Same
4	4	Additives should conform with an approved specification.			3.4	Specifications for the Identity and purity of food additives	Same

[1] The three Codex documents that outline the principles and procedures for the use of additives in Codex Standards are compared to show where differences in recommendation are occurring. The first column of the table provides a number to each row for ease of identification and use during upcoming discussions,. The next two broad columns outline, by paragraph, the General Principles for the Use of Food Additives and the procedure listed in the Codex Procedural Manual. The third broad column aligns the paragraphs of the Preamble to the GSFA with the related paragraphs in the previous two documents. The final column, Evaluation, indicates if the corresponding paragraphs present the same principles and procedures or if they differ significantly.

[2] General Principles for the Use of Food Additives, CAC/MISC 1-1972.

[3] Codex Alimentarius Procedural Manual, 13th Edition, Relations between Commodity Committees and General Committees, pp 95 – 96, 2003.

[4] General Standard for Food Additives, CODEX STAN 192-1995, Rev. 4 – 2003, Preamble, pp. 1 – 5.

Table para	General Principles for the use of Food Additives[2]		Codex Procedural Manual[3]		Preamble to the General Standard for Food Additives[4]		Evaluation
5	5	Use of additives is justified where they serve one or more of the following purposes (a – d) and only where these purposes can not be achieved by other means which are economically and technologically practicable and do not present a hazard to the consumer.			3.2	Use of additives is justified where they serve one or more of the following purposes (a – d) and only where these purposes can not be achieved by other means which are economically and technologically practicable and do not present a hazard to the consumer.	Same
6	5.a	to preserve the nutritional quality of the food; an intentional reduction would be justified in sub-para b and also where the food does not constitute a significant item of a normal diet.			3.2.a	to preserve the nutritional quality of the food; an intentional reduction would be justified in sub-para b and also where the food does not constitute a significant item of a normal diet.	Same
7	5.b	to provide necessary ingredients for foods manufactured for consumers having special dietary needs.			3.2.b	to provide necessary ingredients for foods manufactured for consumers having special dietary needs.	Same
8	5.c	to enhance the keeping quality or stability of a food or improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food or to deceive the consumer			3.2.c	to enhance the keeping quality or stability of a food or improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food or to deceive the consumer	Same
9	5.d	to provide aid in the manufacture, processing, preparation, treatment, packing, transport or storage of food.			3.2.d	to provide aid in the manufacture, processing, preparation, treatment, packing, transport or storage of food.	Same
10	6	Approval for inclusion of an additive should:					

Table para	General Principles for the use of Food Additives[2]		Codex Procedural Manual[3]		Preamble to the General Standard for Food Additives[4]		Evaluation
11	6.a	as far as possible be limited to specific foods for specific purposes and under specific conditions,			5.a	FCS is hierarchical	See paragraph 8 of text
12	6.b	be at the lowest level of use necessary to achieve the desired effect,			1.4 3.3a	Additives covered by this standard and their maximum levels are based in part on the commodity standards, or upon the request of governments. the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect	See paragraph 9 of text
13	6.c	as far as possible take into account the ADI or equivalent assessment and the probable daily intake of it from all sources.			3.1.b	Inclusion of an additive shall take into any ADI or equivalent assessment and its probable intake from all sources.	Same
14			Para 1	Commodity committees should prepare a section on additives in each draft commodity standard. This section should include the names of additives technologically necessary or which are widely permitted for use.	1.2	Standard set forth the conditions which permit additive use in all foods. The additive provision of commodity standards shall be included in and superseded by this standard.	See paragraph 10 of text
15			2	All provisions in commodity standards should be referred to CCFAC after Step 5.			
16			3	All provisions will require to be endorsed by the CCFAC on the	7.2	Revision of the Standard: Proposed revisions may be	See paragraph

Table para	General Principles for the use of Food Additives[2]		Codex Procedural Manual[3]		Preamble to the General Standard for Food Additives[4]		Evaluation
				basis of technological justifications submitted by the commodity committees and of the recommendations of JECFA concerning safety-in-use.		initiated by Codex Committees, Member States or the Commission. Supporting information shall be provided to CCFAC and may include:	11 of text
17			4	Provisions for additives should indicate the INS, the ADI, technological justification, proposed level and whether the additive was previously endorsed.		- Specifications for the additive - Intended food category and use level, - JECFA summary of the additive, - Technological justification	
18			5	Commodity standards at Step 3 should contain a statement that the provisions are subject to endorsement by CCFAC			
19			6	When establishing provisions for food additives, committees should follow the General Principles for the use of Food Additives and the Preamble of the GSFA. Full explanation should be provided for any departure from the above recommendations.			See para 12 of text
20			7	When an active commodity committee exists, proposals for the use of additives in any commodity standard should be prepared by the committee concerned.	7.2	Proposed revisions of this Standard may be initiated by recommendations by Codex Committees, Codex Member States, or the Codex Commission. The CCFAC shall consider all proposed amendments to this	See paragraph 13 of text

Table para	General Principles for the use of Food Additives[2]		Codex Procedural Manual[3]		Preamble to the General Standard for Food Additives[4]		Evaluation
						Standard.	
21			8	When no active commodity committee exists, proposals for new additive provisions should be forwarded directly by member countries to CCFAC.			
22			9	GMP means that:	3.3	All additives shall be used under conditions of GMP which include the following:	Same
23			9.i	the quantity of the additive does not exceed the amount required to accomplish its intended physical, nutritional or other technical effect,	3.3.a	the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect.	Same
24			9.ii	the quantity of the additive that becomes a component of the food as a result of it use in manufacturing, processing or packaging and is not intended to accomplish any physical or other effect in the food is reduced to the extent reasonably possible;	3.3.b	the quantity of the additive that becomes a component of the food as a result of its use in manufacturing, processing or packaging and is not intended to accomplish any physical or other effect in the food is reduced to the extent reasonably possible;	Same
25					3.3.c	the additive is prepared and handled in the same way as a food ingredient.	
26			9.iii	the additive is of appropriate food grade quality.			
27					1.3	Food categories or individual food items where the use of food additives are not allowed or are restricted are defined by this	The following paragraphs are not

Table para	General Principles for the use of Food Additives[2]		Codex Procedural Manual[3]		Preamble to the General Standard for Food Additives[4]		Evaluation
						standard.	present in the other two documents
28					2	Definitions	
29			pg. 49		2.a	Food additive	same
30					2.b	Acceptable Daily Intake	
31					2.c	Acceptable Daily Intake "not specified"	
32					4	Carry-over of food additives into foods	
33					4.1	Compliance with the Carry-over Principle	
34					4.1.a	the additive is permitted in the raw materials or other ingredients (including additives)	
35					4.1.b	the amount of the additive in the raw materials does not exceed the maximum amount so permitted,	
36					4.1.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 ingredients under proper technological conditions or manufacturing practices.	
37					4.2	Ingredients and raw materials as	

Table para	General Principles for the use of Food Additives[2]		Codex Procedural Manual[3]		Preamble to the General Standard for Food Additives[4]		Evaluation
						carriers for additives (ALINORM 97/12, para 44)	
38					5	Food Category System – (refers to Annex B in footnote)	Unique to GSFA
39					5.b	FCS is based on product descriptors of foodstuffs as marketed,	
40					5.c	FCS takes into consideration the carry-over principle,	
41					5.d	FCS is used to simplify the reporting of food additive uses for assembling this Standard	
42					6	Format of the Standard	

APPENDIX IV

(PROPOSED DRAFT REVISION)

GENERAL STANDARD FOR FOOD ADDITIVES

CODEX STAN 192

PREAMBLE

1. SCOPE

1.1 Food Additives Included in this Standard

Only the food additives listed herein are recognized as suitable for use in foods in conformance with the provisions of this Standard.[1] Only food additives that have been assigned a full Acceptable Daily Intake (ADI) or given an equivalent safety assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)[2] and an International Numbering System (INS) designation by Codex are included in this Standard. The use of additives in conformance with this standard is considered to be technologically justified.

1.2 Foods in Which Additives May Be Used

This Standard sets forth the conditions under which food additives may be used in all foods, whether or not they have previously been standardized by Codex. The use of additives in foods standardized by Codex is subject to the conditions of use established by the Codex commodity standards and this standard. The food additive provisions of Codex commodity standards shall be included in and superseded by the provisions of this Standard. Codex commodity committees have the responsibility and expertise to appraise and justify the technological need for the use of additives in foods subject to a commodity standard. The information given by the commodity committees may also be taken into account by the Codex Committee on Food Additives and Contaminants when considering food additive provisions in similar non-standardized foods. When a food is not covered by a commodity committee, Codex Committee on Food Additives and Contaminants will appraise the technological need.

1.3 Foods in Which Additives May Not Be Used

Food categories or individual food items ~~where~~ **in which** the use of food additives is not allowed or is restricted are defined by this Standard.

1.4 Maximum Levels of Use for Food Additives

The primary objective of establishing maximum levels of use for food additives in various food groups is to ensure that the intake of an additive from all its uses does not exceed its ADI.

The food additives covered by this Standard and their maximum levels of use are based in part on the food additive provisions of previously established Codex commodity standards, or upon the request of governments after subjecting the requested maximum levels to an appropriate method for verifying the compatibility of a proposed maximum level with the ADI.

Annex A of this Standard may be used as a first step in this regard. The evaluation of actual food consumption data is also encouraged.

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[1] Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is substantially complete.

[2] An index of food additives with their current ADI status, the year of their most recent JECFA evaluation, their assigned INS numbers, etc., are available at the Joint Secretariat's web pages at http://www.fao.org/es/ESN/jecfa/index_en.stm for FAO and http://www.who.int/pcs/jecfa/jecfa.htm for WHO. [under development]

2. DEFINITIONS

a) ***Food additive*** means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities.[3]

b) ***Acceptable Daily Intake (ADI)*** is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk.[4]

c) ***Acceptable Daily Intake "Not Specified" (NS)***[5] is a term applicable to a food substance of very low toxicity for 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 the above reason, and for reasons stated in individual JECFA evaluations, establishment of an acceptable daily intake expressed in numerical form is not deemed necessary by JECFA. An additive meeting the above criterion must be used within the bounds of good manufacturing practice as defined in section 3.3 below.

d) ***Maximum level of use*** of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food.

The maximum level will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.

3. GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES[6]

The use of food additives in conformance with this Standard requires adherence to all the principles set forth in Sections 3.1 – 3.4.

3.1 Food Additive Safety

a) Only those food additives shall be endorsed and included in this Standard that, so far as can be judged on the evidence presently available from JECFA, present no appreciable health risk to consumers at the levels of use proposed.

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3 Codex Alimentarius Procedural Manual.

4 Principles for the Safety Assessment of Food Additives and Contaminants in Food, World Health Organization, (WHO Environmental Health Criteria, No. 70), p. 111 (1987). For the purposes of this Standard, the phrase "without appreciable health risk" means that there is a reasonable certainty of no harm to consumers if an additive is used at levels that do not exceed those in this Standard. The provisions of this Standard do not sanction the use of an additive in a manner that would adversely affect consumer health.

5 For purposes of this Standard, the phrase acceptable daily intake (ADI) "not limited" (NL) has the same meaning as ADI "not specified". The phrase "acceptable ADI" refers to an ADI which is more appropriately limited by the level of treatment of the food, rather than on a mg additive per kg body weight per day basis (see, Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives at http://jecfa.ilsi.org).

6 General Principles for the Use of Food Additives were originally adopted by the Ninth Session of the Codex Alimentarius as a Codex Advisory Text (para. 295, ALINORM 72/35). Pertinent portions of the Text are incorporated as an integral part of this Standard, suitable modifications having been made as necessary with respect to the present context.

b) The inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake[7] from all food sources. Where the food additive is to be used in foods eaten by special groups of consumers (e.g., diabetics, those on special medical diets, sick individuals on formulated liquid diets), account shall be taken of the probable daily intake of the food additive by those consumers.

The quantity of an additive added to food is at or below the maximum level and is the lowest level necessary to achieve the intended technical effect. The maximum level may be based on the intake assessment of Codex member countries or upon a request by the CCFAC to JECFA for an independent evaluation of national intake assessments.

3.2 Justification for the Use of Additives

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable:

a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;

b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;

c) to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;

d) to provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3.3 Good Manufacturing Practice (GMP)[8]

All food additives subject to the provisions of this Standard shall be used under conditions of good manufacturing practice, which include the following:

a) the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;

b) 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 technical effect in the food itself, is reduced to the extent reasonably possible; and,

c) the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.

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7 Codex member countries may provide the Codex Committee on Food Additives and Contaminants (CCFAC) with intake information that may be used by the CCFAC in establishing maximum levels of use. Additionally, the JECFA, at the request of the CCFAC, will evaluate intakes of additives based on intake assessments submitted by Codex member countries responding to a call for data. The CCFAC will consider the JECFA evaluations when establishing the maximum use levels for additives.

8 For additional information, see the Codex Alimentarius Commission Procedural Manual.

3.4 Specifications for the Identity and Purity of Food Additives

Food additives used in accordance with this Standard should be of appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission[9] or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies. In terms of safety, food grade quality is achieved by conformance of additives to their specifications as a whole (not merely with individual criteria) and through their production, storage, transport, and handling in accordance with GMP.

4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS[10]

4.1 Compliance with the Carry-over Principle

Other than by direct addition, an additive may be present in a food as a result of carry-over from a food ingredient, subject to the following conditions:

a) The additive is acceptable in the raw materials or other ingredients (including food additives) according to this Standard;

b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified in this Standard.

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 ingredient under proper technological conditions or manufacturing practice.

4.2 Ingredients and Raw Materials as Carriers for Additives[11]

An additive may be used in a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this standard.

4.3 Foods for Which the Carry-over Principle Does Not Apply

a) Infant formulae, follow-up formulae, and formulae for special medical purposes for infants (Food Category 13.1).

b) Complementary foods for infants and young children (Food Category 13.2).

5. FOOD CATEGORY SYSTEM[12]

The food category system is a tool for organizing food additive uses in this Standard. The food category system applies to all foodstuffs.

The food category descriptors are not to be legal product designations nor are they intended for labelling purposes.

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9 An index (CAC/MISC 6 – 2001) of all specifications adopted by the Codex Alimentarius Commission, as well as the year of adoption, is available at the Codex website (http://www.codexalimentarius.net/web/standard_list.do?lang=en). These specifications, prepared by the JECFA, are also being published in the FAO Food and Nutrition Paper series as the "Compendium of Food Additive Specifications," which consists of two volumes published in 1992 and a subsequent series of addenda. The specifications are also available at the JECFA website (http://www.fao.org/es/esn/Jecfa/database/cover.htm). However, neither this website nor the addenda to the Compendium contain information that shows which specifications have been adopted by Codex.

10 The principle relating to the carry-over of food additives into foods (the "Carry-Over Principle") addresses the presence of additives in food as a result of the use of raw materials or other ingredients in which these additives are used. The Codex Alimentarius Commission at its 17th Session (1987) adopted a revised statement of the principle as a Codex Advisory Text. The Carry-Over Principle applies to all foods covered by Codex standards, unless otherwise specified in such standards.

11 See ALINORM 97/12, para. 44.

12 Annex B to this Standard.

The food category system is based on the following principles:

a) The food category system is hierarchical, meaning that when an additive is recognized for use in a general category, it is recognized for use in all its sub-categories, unless otherwise stated. Similarly, when an additive is recognized for use in a sub-category, its use is recognized in any further sub-categories or individual foodstuffs mentioned in a sub-category.

b) The food category system is based on product descriptors of foodstuffs as marketed, unless otherwise stated.

c) The food category system takes into consideration the carry-over principle. By doing so, the food category system does not need to specifically mention compound foodstuffs (e.g., prepared meals, such as pizza, because they may contain, *pro rata*, all the additives endorsed for use in their components), unless the compound foodstuff needs an additive that is not endorsed for use in any of its components.

d) The food category system is used to simplify the reporting of food additive uses for assembling and constructing this Standard.

6. DESCRIPTION OF THE STANDARD

This Standard consists of three main components:

a) Preamble

b) Annexes

i. Annex A is a guideline for considering maximum use levels for additives with numerical JECFA ADIs.

ii. Annex B is a listing of the food category system used to develop and organize Tables 1, 2, and 3 of the standard. Descriptors for each food category and sub-category are also provided.

Annex C is a cross-reference of the food category system and Codex commodity standards.

c) Food Additive Provisions

i. Table 1 specifies, for each food additive or food additive group (in alphabetical order) with a numerical JECFA ADI, the food categories (or foods) in which the additive is recognized for use, the maximum use levels for each food or food category, and its technological function. Table 1 also includes the uses of those additives with non-numerical ADIs for which a maximum use level is specified.

ii. Table 2 contains the same information as Table 1, but the information is arranged by food category number.

iii. Table 3 lists additives with non-numerical JECFA ADIs that are acceptable for use in foods in general when used at *quantum satis* levels and in accordance with the principles of good manufacturing practice described in Section 3.3 of this preamble.

The Annex to Table 3 lists food categories and individual food items excluded from the general conditions of Table 3. The provisions in Tables 1 and 2 govern the use of additives in the food categories listed in the Annex to Table 3.

Unless otherwise specified, maximum use levels for additives in Tables 1 and 2 are set on the final product as consumed.

Tables 1, 2, and 3 do not include references to the use of substances as processing aids.[13]

[13] Processing Aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product: Codex Alimentarius Commission Procedural Manual.

7. REVIEW AND REVISION OF THE STANDARD

7.1 Review

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

7.2 Revision

The food additive provisions of this Standard shall be amended as necessary. Proposed revisions may be initiated by recommendations of Codex Committees, Codex member countries, or the Codex Alimentarius Commission. Information to support amendment of this Standard 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 enumerated in Section 3.2 of this Standard;
- Maximum use levels for the food additive in the specified food categories:
    - For additives with a numerical ADI, a numerical maximum level for each specified use;
    - For additives with an ADI Not Specified, 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;
- A justification of the maximum use levels from a technological point-of-view; and an indication, by means of an exposure assessment, that this level meets the safety requirements enumerated in Section 3.1 of this Standard.
- 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 this Standard proposed by Codex Committees, Codex member countries, or the Codex Alimentarius Commission.