

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 7(b)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-fifth Session

Arusha, Tanzania, 17 - 21 March 2003

PROPOSED DRAFT REVISED PREAMBLE TO THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 15 December 2002** as follows: Netherlands Codex Contact Point, Ministry of Agriculture, Nature Management and Fisheries, P.O. Box 20401, 2500 E.K., The Hague, The Netherlands (Telefax: +31.70.378.6141; E-mail: info@codexalimentarius.nl, 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).

I. SCOPE AND PURPOSE

1. The 34th Session of the Codex Committee on Food Additives and Contaminants (CCFAC) agreed to install a drafting group¹ under the direction of France and the United States of America to elaborate proposed draft revisions to the Preamble of the Codex General Standard for Food Additives (GSFA) to address the following:

- Clarify the relationship between the GSFA and Codex commodity standards
- Elaborate on appropriate criteria in the Preamble for establishing additive provisions in the GSFA
- Reconsider the criterion that reporting of the use of an additive by a Member State in a food category is prima facie evidence for the technological need for the use of an additive.
- Reconsider the principle that if at least two Codex Member States permit the use of the additive up to the maximum level proposed in Tables 1 and 2 in foods representative of the category, that is evidence of trade of these foods, taking into account the requirements for additives provisions in the Procedural Manual as regards Codex commodity standards.²

¹ Australia, Brazil, Canada, Italy, Japan, Netherlands, New Zealand, Norway and Switzerland

² ALINORM 03/12, para. 51

II. BACKGROUND

A. Origin and Scope of the GSFA

2. A brief description of the origin and scope of the Codex General Standard for Food Additives is provided in Annex I. The Annex summarizes the important decisions of the Codex Alimentarius Commission (CAC) and the CCFAC relating to the development of the GSFA. These decisions are the basis upon which the GSFA has been elaborated.

B. Principles for the Development of the GSFA

3. The 24th CCFAC (1992)³ agreed to the following principles for developing the GSFA:

- The format of the GSFA should be based on functional class titles as provided in the Codex International Numbering System (INS) for Food Additives and also on food categories initially using the CIAA (Confederation des Industries Agro-Alimentaires del'UE) system.
- The GSFA should cover food additive usage in all foods (standardized and non-standardized).
- All additives in the INS list should be included, beginning with those evaluated by JECFA; other food additives should be included only after JECFA completes its safety evaluation.
- The Budget Method⁴ should be used as an initial screening tool to help establish the maximum level of use for an additive. Codex Guidelines for the Estimation of Food Additive Intake should also be used.
- The GSFA should define foods or food categories where the use of food additives is restricted or prohibited.
- Acceptable Daily Intakes (ADIs) should not be used to prioritize additives for consideration.

4. The 24th CCFAC agreed that the GSFA should contain a preamble that includes the General Principles for the Use of Food Additives and refers to appropriate sections of the Codex Procedural Manual on the use of food additives.

5. The 25th CCFAC (1993) had before it the first complete draft of the GSFA with a preamble, annexes and schedules of food additive uses.⁵

6. It is important to note that at the earliest stages in the development of the GSFA, the Denner Paper⁶ and subsequent sessions of the CCFAC identified two significant considerations for elaborating the GSFA:

- a) the need for translating JECFA ADIs into maximum use levels for food additives, and
- b) the application of the principles of technological need and good manufacturing practices.

7. The CCFAC's ad hoc GSFA Working Group has developed several "tools" (food category system, collection of source data, compression of source data, quality control of source data, intake assessment, priority ranking of additives for discussion, technological need and justification, and format of the standard) for elaborating the draft GSFA so that it is consistent with the committee's instructions from the CAC. The following is a brief description of the evolution of each of these "tools."

³ ALINORM 93/12

⁴ Hansen, S.C. (1979) Conditions for Use of Food Additives Based on a Budget for an Acceptable Daily Intake. *J. Food Protection*. 42, 429-434.

⁵ CL 1992/18-FAC

⁶ CX/FA 89/16

Food Category System

8. The 24th CCFAC (1992) agreed that the food category system for the GSFA should initially be based on the CIAA system. Accordingly, comments were requested on the CIAA system⁷ and considered by the 25th CCFAC. The committee reaffirmed that the categorization system should include all foods in international trade and requested that specific recommendations be submitted to amend the food category system accordingly. Subsequently, the committee has revised the food category system several times to meet the evolving needs of the GSFA.

9. The 28th CCFAC (1996) accepted the offer of the Belgian Delegation, in co-operation with the CIAA, to propose amendments to the Preamble to describe more thoroughly the principles and application of the food category system.

10. The 29th CCFAC (1997) endorsed revisions to the Preamble⁸ to include principles and application of the GSFA's food category system. The revisions were subsequently adopted by the 22nd CAC (1997).

11. At the request of the 33rd CCFAC (2001) a discussion paper⁹ was prepared for consideration by the 34th CCFAC that contained a full description of the GSFA food categories and proposed revisions to the food category system.

12. The 34th CCFAC (2002) agreed to several revisions to the Food Category System and established a drafting group under the direction of the United States, with the assistance of Australia, India, Japan, Switzerland, Thailand, CEFS, IBFAN, IDF, IFMA, IOCCC, ISDI, and OIV to review the written comments and the discussion at the meeting with a view towards elaborating an amended version of the food category system for circulation, comment and further consideration at its next meeting.¹⁰

Source Data for the GSFA

13. The initial draft GSFA focused on food additive provisions for antioxidants and preservatives compiled from Codex commodity standards.¹¹ The 24th CCFAC (1992) agreed that all additives in the INS list should be included, beginning with those evaluated by JECFA; other food additives should be included only after JECFA completes its safety evaluation. Subsequently, the CCFAC collected and published proposals¹² from Member States for all additives assigned an ADI by JECFA. At the completion of the 30th CCFAC (1998), the committee had systematically collected and assembled this information by additive functional class in response to several circular letters¹³ requesting Member States to provide additive use information and information on the technological need and justification for their proposed uses.

Compression of the Source Data

14. During the 27th CCFAC's (1995) discussion of the revised worksheets for antioxidants and preservatives, many Delegations expressed concern about the enormous quantity of information contained in the 'source worksheets.' It was apparent to the committee that a means to condense or compress all the reported maximum use levels must be found in order to proceed with the development of the standard. Various Delegations argued for the minimum reported use level, the average value, the median, and the maximum reported use level. The 27th CCFAC agreed that the next version of the proposed draft standard

⁷ CL 1992/11-FAC

⁸ CX/FAC 97/6

⁹ CX/FAC 02/6

¹⁰ ALINORM 03/12, para. 54

¹¹ CL 1990/26-FAC

¹² CX/FAC 96/8, CX/FAC 97/8, CX/FAC 98/8

¹³ CL 1994/11-FAC, CL 1995/15-FAC, CL 1996/14-FAC, CL 1997/9-FAC

should contain the reported range of use levels for an additive in a given food category. The United States Delegation, as chair of the GSFA Working Group, volunteered to revise the worksheets by removing redundant information and to implement the other recommendations of the CCFAC in time for its 28th session.

15. The ad hoc GSFA Working Group at the 28th CCFAC (1996) agreed on the following general principles¹⁴ for simplifying or compressing the source data:

- First Level: Remove all redundant provisions
- Second Level: Remove information on sources, combine identical entries, and retain the highest and lowest maximum use level reported for a food category.
- Third Level: Remove food category suffixes and combine entries from the same hierarchical level of food category designation regardless of suffix. Retain highest and lowest maximum use levels reported.
- Fourth Level: Sequential combining of entries within the same hierarchical level of food category designation.

The committee agreed that the compressed information provided a valuable tool for the further development of the GSFA and stressed that the compressed information was not intended to be the final standard, but rather it was intended to help the Committee elaborate the GSFA.¹⁵

16. The 28th CCFAC requested that the United States prepare a discussion paper on the application of the principles and tools already established for the data collected on additive uses, and document with explanatory notes the application of the principles and tools used to develop the draft general standard.¹⁶

17. The United States Delegation presented a discussion paper¹⁷ to the 29th CCFAC (1997) providing a detailed description of how the compressed Schedules 1 and 2 (now designated as Tables 1 and 2) were constructed from information submitted by Member States and the food additive provisions in Codex commodity standards. Briefly, the discussion paper expanded on the principles agreed to by the Working Group during the 28th CCFAC. One change was that the highest maximum use level in the broadest food category was reported in the compressed schedules. The Working Group took this approach to provide the least trade restrictive draft standard for further discussion and elaboration by the committee.

18. The discussion paper¹⁷ used the following principles for the development of the draft standard for additives with numerical ADIs assigned by JECFA:¹⁸

- Numerical use levels take precedence over a GMP use level, with the maximum numerical level reported in the draft GSFA;
- Within a food category, the use level reported for a “ready-to-eat” food takes precedence over the reported use in a “semi-finished” food (e.g., dry mix, on the fat basis, in the creaming mixture (for cheese));
- The reported use levels within a food category are expanded or compressed as necessary so that the maximum use level in the broadest food category supported by the source data is reported in the GSFA;
- Within a food category, the uses for “group” additives (i.e., additives with JECFA group ADIs (e.g., benzoates, phosphates)) are considered together; and

¹⁴ CX/FAC 96/7

¹⁵ ALINORM 97/12, para. 37

¹⁶ ALINORM 97/12, para. 48

¹⁷ CX/FAC 97/7

¹⁸ Additives with “not specified” or “not limited” ADIs (i.e., non-numerical ADIs) were considered together with additives with numerical ADIs in Schedules 1 and 2. The additives with non-numerical ADIs were moved to Table 3 at the 29th CCFAC (ALINORM 99/12A, Appendix IV).

- Provisions for different functional effects (e.g., antioxidant, preservative, stabilizer, thickener, sweetener) are considered separately. However, as of the 31st CCFAC (1998), the provisions for different functional effects within a given food category are considered together.¹⁹

19. The discussion paper¹⁷ also provided principles for establishing provisions for additives with non-numerical ADIs. In this case, use levels of GMP should take precedence over a numerical use level. This procedure was discontinued with the creation of Table 3.²⁰ As a result, draft maximum use levels assigned to additives with non-numerical ADIs that are listed in Tables 1 and 2, include GMP and numerical limitations. Discussion at the 34th CCFAC (2002) included a proposal to assign, as a matter of principle, GMP maximum use levels to all additives with non-numerical ADIs listed in Tables 1 and 2.

20. The 30th CCFAC (1998) subsequently agreed that all provisions in Tables 1 and 2 would be condensed and simplified, where appropriate, to have one entry for each food category, for each food additive with multiple functions and for additives with group ADIs. When simplifying Tables 1 and 2, numerical use levels would be retained in preference to GMP levels for additives with numerical ADIs. Where there were no numerical levels, comments would be requested on provisions with GMP levels with a view towards establishing numerical levels.²¹

21. The 34th CCFAC (2002) agreed that as a matter of principle, food additives assigned a numerical ADI by JECFA should have a numerical limitation on their use in the GSFA. In this regard, the committee agreed to hold all GMP provisions for these additives (i.e., with numerical ADIs) at Steps 3 or 6 so that specific numeric levels of use could be provided before its 35th Session. The committee agreed that all GMP maximum levels for the additives with numerical ADIs would be deleted from the draft GSFA if this information were not provided by its 35th session. The committee also agreed to consider the application of these principles to already adopted additive provisions at a future meeting.²²

Quality Control Working Group

22. The 31st CCFAC (1999) noted the need for a small working group to consider the provisions in Tables 1 and 2 of the GSFA between its sessions to identify errors and to confirm technological need and maximum use levels for these provisions. The Delegations of Australia, Brazil, Japan South Africa, United States, and the Observer from the EC agreed to participate to represent their respective continents. It was agreed that input from industry and consumer organizations would also be provided. This Working Group was reestablished by the 32nd and 33rd CCFAC to complete the quality control review of all the source data for additives assigned numerical ADIs by JECFA. The reports of the Quality Control Working Group are available.²³

23. The information provided by the Quality Control Working Group is used by the committee's ad hoc GSFA Working Group in its discussion of the provisions in the draft GSFA.

Intake Assessment

24. As noted above, from its earliest discussions of the GSFA, the CCFAC has recognized the need to provide a mechanism to translate the JECFA ADIs into maximum use levels for food additives. Recognizing the difficulty of assessing consumer intakes of food additive from consumption of foods traded internationally, the 24th CCFAC (1992) agreed that the Budget Method would be used as an initial screen to

¹⁹ CX/FAC 99/6.

²⁰ ALINORM 99/12A, Appendix IV.

²¹ ALINORM 99/12, para. 28

²² ALINORM 03/12, para. 60

²³ CL 1999/15-FAC; CL 2000/33-FAC. 34th CCFAC CRD 1-Appendix II

translate the JECFA ADIs into maximum levels of use. As a result, the proposed draft GSFA circulated to the 25th CCFAC (1993) included Annex A to the Preamble which contained a modified Budget Method.

25. With regard to Annex A, some Delegations²⁴ expressed their view that the Budget Method was not applicable to Asian countries because it was based on Western dietary habits. In response to these views, the 25th CCFAC agreed that for assessing additive intake, food intake data should be provided whenever possible, but that the Budget Method could be used as a first 'screening method' to determine whether an intake assessment was necessary for establishing the appropriateness of proposed use levels.

26. Within the context of its discussion of risk assessment procedures used by the CAC and its subsidiary bodies, the 26th through 29th sessions of the CCFAC explored expansion of Annex A to the Preamble to include a tiered approach for screening proposed additive maximum use levels in the GSFA.^{25, 26, 27, 28, 29}

27. The 29th CCFAC (1997) agreed that the proposed tiered approach, while helpful, was not adequate for furthering the development of the GSFA. Therefore, the CCFAC agreed that Annex A should be revised to incorporate only the Budget Method and to refer additives to JECFA for the evaluation of intake data, as appropriate.³⁰

28. The 29th CCFAC reviewed the results of the application of the Budget Method to all of the additives with numerical ADIs in the draft GSFA. The committee agreed to forward provisions for all of the additives for which the Budget Method screen did not present safety concerns to the Commission for adoption at Step 8.³¹

29. The 29th CCFAC agreed to request that JECFA perform intake assessments for benzoates, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), sulfites, and tertiary-butylhydroxyquinone (TBHQ) based on the levels of maximum use in the proposed draft GSFA. These additives were identified because several delegations expressed concern that the draft provisions for these additives may contribute significantly to their intake exceeding their ADI.

30. The 49th JECFA, meeting in June of 1997, outlined its approach for the assessment of intake data for food additives.³² Noting the 29th CCFAC's request for a priority assessment of intake of the five additives, the JECFA proposed that information on national assessments of the intake of the five additives be requested from countries and that an evaluation of the assessments received be undertaken at its next meeting.

31. The 51st JECFA (1998) reviewed national intake data on benzoates, BHA, BHT, sulfites, and TBHQ.

32. The 30th CCFAC (1998) discussed a revised Annex A that contained a description of the application of the Budget Method and agreed that it should be revised and considered at its next session.

²⁴ ALINORM 93/12a, para. 35

²⁵ ALINORM 95/12, para. 30

²⁶ CX/FAC 95/3

²⁷ Application of Risk Analysis to Food Standards Issues, Report of the Joint FAO/WHO Expert Consultation, Geneva Switzerland, March 13-17, 1995 (WHO/FNU/FOS/95.3).

²⁸ CX/FAC 96/6

²⁹ CX/FAC 97/9

³⁰ ALINORM 97/12A, paras. 31-34

³¹ ALINORM 99/12A, para 35

³² WHO TRS No. 884, Geneva (1999)

33. The 30th CCFAC also agreed to request JECFA review national intake data on annatto extract, canthaxanthin, erythrosine, and iron oxides.³³ The 53rd JECFA reviewed national food intake data on these substances based on levels in the draft GSFA.

34. The 31st CCFAC (1999) agreed that the revised Annex A based on the Budget Method was a useful screening tool and that it should be incorporated into the General standard. The revised Annex A was subsequently adopted by the 24th CAC (2001).

35. In summary, the CCFAC has established the following procedure for determining whether the maximum levels for a food additive in the draft GSFA may lead to consumer intakes that exceed the numerical ADI for the additive:

- 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 provisions are forwarded for adoption at Step 8.
- At the request of Member States, 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.

Priority Ranking of Additives with Numerical JECFA ADIs

36. The ad hoc GSFA Working Group that met prior to the 31st CCFAC established a priority ranking of all additives with numeric ADIs.³⁴ The priority ranking contained all of the additives in CX/FAC 99/6. The priority ranking places the additives into eight groups based on comments received in response to CX/FAC 99/6 and is intended to aid the committee's discussion of the GSFA with a view towards advancing food additive provisions in the draft GSFA. The Working Group found that this ranking of additives was useful, and agreed that it would provide a means of systematically addressing each of the additives in turn.

Technological Justification and Need

37. As noted above, the question of how to justify the technological need for the use of additives was raised early in the development of the GSFA. The issue of justifying the technological need for the use of additives within the Codex system actually predates the CCFAC's work on the GSFA.

38. The 9th Session of the CAC (1972) adopted³⁵ as an advisory text General Principles for the Use of Food Additives.³⁶ These include the following principles for the technological justification for food additive provisions:

"The use of food additives is justified only where they serve one or more of the purposes set out from (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

- (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;

³³ ALINORM 99/12, para. 28

³⁴ 31st CCFAC, CRD 1, App. 1

³⁵ ALINORM 72/35, para. 295

³⁶ Codex Alimentarius, Volume 1A, Section 5.1 (2000)

(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 so change the nature, substance or quality of the food 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."

39. The 2nd Session of the Coordinating Committee for Asia (1979) held extensive discussions concerning the possible use of colors and flavors in foods to mask inferior quality and resultant possible consumer deception. In response, the 13th CAC (1979) requested the Codex Committee on Food Additives (CCFA) to develop guidelines for Codex commodity committees for supplying appropriate information to the CCFA to use as a basis for endorsing food additive provisions in light of technological justification and consumer protection. The need for the CCFA to develop guidelines for the establishment of food additive provisions was further considered by the 14th, 15th and 16th Sessions of the committee. Subsequently, the 15th CAC (1983) agreed that the guidance contained in the Procedural Manual and the Codex General Principles for the Use of Food Additives was adequate.

40. Recommendation 7 of the Denner Paper (See Annex 1) recognized that "in the interest of free trade there should be greater recognition of, and tolerance shown towards, the variability of technological need among different nations and also with time. There should be a corresponding decrease in government prohibitions on additives in individual foods and a greater reliance on informative labeling, so that consumers can choose for themselves which type of product they wish to buy."

41. Discussion of technological need since 1979 ultimately resulted in the 25th CCFAC³⁷ (1993) agreeing to a number of recommendations for revising the Proposed Draft Preamble of the GSFA including the addition of a new section on technological need and justification.

42. The Preamble was modified to establish that the use of food additives is justified only when such use has an advantage, does not present a hazard to health to the consumer, does not mislead the consumer, and serves one or more of the technological functions set out from (a) through (d) from the Codex General Principles for the Use of Additives (para. 38), and only where these objectives cannot be achieved by other means which are economically and technologically practicable.

43. The 26th CCFAC (1994) agreed to the offer of Iceland and New Zealand to prepare a discussion paper on the consideration of technological justification and need for its next session. Consistent with the Denner Paper (Annex I), the discussion paper³⁸ centered on the need to accommodate differences in technological need among countries within the context of Codex's overall objectives of ensuring safety and facilitating international trade. The discussion paper established the principle that approval of a food additive by a Member State should, in the first instance, be taken as evidence of technological justification and need. Furthermore, in deciding how 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.³⁹

³⁷ ALINORM 93/12A

³⁸ CX/FAC 95/5

³⁹ ALINORM 97/12A, para 35

44. The 27th CCFAC noted that differences in technological need should be recognized within the perspective of the overall objectives of ensuring safety and facilitating international trade. The committee also agreed that whenever possible, technological need should be addressed through consideration of additive classes, instead of a additive-by-additive approach.⁴⁰

45. During the GSFA WG meeting at the 28th CCFAC (1996), the New Zealand Delegate presented a proposed step-wise procedure for applying principles for justifying technological need toward the development of the GSFA. The 28th CCFAC agreed that New Zealand, Australia, and Iceland would further elaborate the application of the principles of technological justification and need by drafting a discussion paper expanding on the step-wise procedure discussed during the GSFA WG.

46. The 29th CCFAC (1997) discussed a paper⁴¹ on technological need that proposed a step-wise procedure for the evaluation of technological need. The proposal was based on the following decisions of the 26th and 27th CCFAC:

- i) Recognition that technological need may differ from one country to another.
- ii) Recognition that technological need should be addressed, whenever possible, through consideration of additive functional classes and not on an additive-by-additive basis.
- iii) Maintenance of a clear distinction between the justification of technological need and additive intake assessment.

47. The paper affirmed that the first premise for establishing the need for the use of an additive is whether a national authority has reported such a use for an additive. If the initial intake screen (e.g., Budget Method) indicates that intake of the additive may exceed the ADI, then a closer examination of the proposed maximum use levels for the additive in all food categories should be undertaken with a view to a formal intake assessment, and subsequent refinement of the maximum use levels based on technological need. The paper envisioned that this process would continue unless the intake assessment could be shown to be compatible with the ADI. The committee agreed to request comments on this paper for consideration by the 30th CCFAC.

48. The 30th CCFAC (1998) agreed to the following procedure to resolve questions 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 States 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 States continue to express concern about the proposed maximum levels, and;
- Circulate the revised draft Tables 1 and 2 for comments:
 - If a Member State 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 State wishes to support a draft maximum use level which has been identified as being of concern by other Codex Members States, data should be presented to demonstrate that the

⁴⁰ ALINORM 95/12A, para 44

⁴¹ CX/FAC 97/10

product could not be made to a satisfactory quality using a lower level of additive or alternative additives that are listed in the GSFA.

49. In summary, international trade is a prerequisite for developing a Codex standard. CCFAC may wish to consider establishing a general criterion for the establishment of food additive provisions in the GSFA that at least 2 countries must support the use of the additive in a particular food category before it can be considered in that particular category.

50. In developing the GSFA, the CCFAC has recognized that technological need may differ from one country to another and that whenever possible, technological need should be addressed through consideration of additive classes (e.g., emulsifier, bulking agent, acidity regulator) and not on an additive-by-additive basis.⁴² That is, the CCFAC should address whether the additive technical effect is appropriate for the foods in which the additive would be used. If the technical effect of the additive is deemed appropriate, then the justification of technological need will have been met.

51. The CCFAC has also recognized that the application of the principles for justifying technological need must be distinct from additive intake assessment.⁴³ However, an important consideration of technological need is the level of use required for the additive to achieve its intended effect. If the additive is present at too low a level, it will not achieve its intended technical effect. Intake assessments should be performed at the level of use at which the additive is optimally effective in achieving its intended technological function.

52. The criteria for technological need set forth in the Procedural Manual, the General Principles for the Use of Food Additives, and the Preamble, as well as CCFAC's principles for resolving questions of technological need should be reviewed with a view towards harmonizing the different approaches and principles.

Format of the Standard

53. The 24th CCFAC (1992)⁴⁴ agreed that the format of the GSFA should be based on functional class titles as provided in the INS and also on the food category system developed for the elaboration of the GSFA.

54. Prior to the 25th CCFAC (1993), the Proposed Draft Codex GSFA⁴⁵ was circulated for comment. The proposed draft standard consisted of five principal sections:

i) Preamble

Annex A: the guidelines for the use of additives in non-standardised foods, which were based on the Budget Method; and

Annex B: cross-reference listing of Codex Standard Numbers, Codex Standard Titles, and Food Categories.

ii) Schedule 1: an alphabetical listing of antioxidants and preservatives by functional class, their maximum use levels and conditions of use in standardised foods;

iii) Schedule 2: a listing of the same data in Schedule 1 arranged by food category;

⁴² ALINORM 95/12A, para. 44

⁴³ ALINORM 97/12, para. 42

⁴⁴ ALINORM 93/12

⁴⁵ CL 1992/18-FAC

iv) Schedule 3: a listing of foods and food categories in which food additives were prohibited.

55. The 26th CCFAC (1994) reaffirmed its agreement to maintain the two-schedule format and by calling for further revision as additional additive use information became available.

56. At the 29th CCFAC (1997), the observer from the European Community proposed that the committee place all additives with JECFA ADIs of ‘not specified’ or ‘not limited’ (i.e., non-numerical) in a separate schedule and endorse their use in foods in general, in accordance with GMP. This schedule would be accompanied by a list of food categories or foods where these additives were not allowed or were further restricted. The CCFAC endorsed this approach and established a list⁴⁶ of approximately 170 additives for use in food in general in accordance with GMP and an annex containing a list of food categories where the use of these additives was further restricted. This annex of food categories⁴⁷ was based on a list that was currently in effect in the European Union. As corollaries to this decision, the committee agreed to cease further development of Schedule 3-formatted information (i.e., a list of foods and food categories in which food additives were prohibited) and to delete all food additive provisions in Schedules 1 and 2 reported in food category 0.0 (Foods in General). The GMP list and its annex were forwarded by the CCFAC to the 22nd CAC at Step 5 with a recommendation for adoption at Step 8. The 22nd CAC subsequently adopted the GMP list of additives at Step 8, and adopted the Annex on an interim basis at Step 8 with a request that the CCFAC review the Annex and report its findings to the next session of the CAC.⁴⁸ The Annex has subsequently been revised, with the latest revision made at the 34th CCFAC (2002)⁴⁹.

57. In response to previous discussions by the CCFAC’s ad hoc GSFA Working Group and in recognition of the large quantity of information that the committee had collected and compiled on additive uses, the 30th CCFAC agreed to the following components for the GSFA:

Preamble

Annex A to the Preamble (Guideline for the Development of Maximum Levels of Use for Food Additives with Numerical ADIs)

Annex B to the Preamble (GSFA Food Category System)

Annex C to the Preamble (Cross-Reference to Codex Commodity Standards and the GSFA Food Category System)

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List A: JECFA “Approved” Food Additives with ADIs and INS Numbers (Including Synonyms). Sorted alphabetically by additive.

List B: JECFA “Approved” Food Additives with ADIs and INS Numbers (Includes JECFA review date and Meeting Number). Sorted by INS Number.

Table 1: Additives Permitted for Use Under Specified Conditions in Certain Food Categories or Individual Food Items.

Table 2: Food Categories or Individual Food Items in Which the Use of Food Additives are Permitted Under Specified Conditions.

Table 3: Additives with Non-numerical ADIs Permitted for Use in Food in General in Accordance with GMP Unless Otherwise Specified.

⁴⁶ ALINORM 97/12A, Appendix IV

⁴⁷ ALINORM 97/12A, Annex to Appendix IV

⁴⁸ ALINORM 97/37, paras. 57 & 59

⁴⁹ ALINORM 03/12, Appendix IV

Annex to Table 3: Food Categories and Individual Food Items Where the Use of Food Additives with Good Manufacturing Practice Limitations on Use are Not Allowed or Restricted.

58. In the new format, Table 1 (sorted alphabetically by additive) corresponds to the previous Schedule 1 format and Table 2 (sorted by food category) corresponds to the previous Schedule 2 format. Similarly, the additive use information in Tables 1 and 2 are identical but differ only in their presentation. The 30th CCFAC also agreed that the technical effects of each additive would be listed together at the beginning of each additive listing in Table 1 and would not be listed in Table 2.

59. The 31st CCFAC (1999) agreed that, even for food categories or individual food items listed in the Annex to Table 3, maximum use levels for additives listed in Table 3 could be established in both Table 1 and Table 2. The committee also agreed that the title of the Annex to Table 3 should be amended as follows: Food Categories or Individual Food Items Excluded from the General Conditions of Table Three.” A statement that “The use of additives listed in Table Three in the following foods is governed by the provision in Tables One and Two” was also added.⁵⁰

III. CRITERIA FOR ESTABLISHING FOOD ADDITIVE PROVISIONS

Introduction

60. The 34th CCFAC agreed that this discussion paper should elaborate on appropriate criteria in the Preamble for establishing additive provisions in the GSFA and reconsider whether the reporting by a Member State of the use of an additive is prima facie evidence of the technological need for the use of an additive.

61. The Codex General Principles for the Use of Food Additives⁵¹ states that the “Approval or temporary approval for the inclusion of a food additive in an advisory list or in a food standard should:

- a) as far as possible be limited to specific foods for specific purposes and under specific conditions;
- b) be at the lowest level of use necessary to achieve the desired effect;
- c) as far as possible take into account any Acceptable Daily Intake, or equivalent assessment, established for the food additive and the probable daily intake of it from all sources. Where the food additive is to be used in foods eaten by special groups of consumers, account should be taken of the probable daily intake of the food additive by consumers in those groups.”

62. Recommendation 7 of the Denner Paper (Annex I) states:

“ In the interests of free trade there should be greater recognition of, and tolerance shown towards, the variability of technological need among different nations and also with time. There should be a corresponding decrease in government prohibitions on additives in individual foods and a greater reliance on informative labelling so that consumers can choose for themselves which type of product they wish to buy.”

63. The 25th CCFAC’s (1993)⁵² deliberations resulted in the inclusion of a section in the Preamble intended to clarify that the maximum use levels in the GSFA are either based on existing provisions in Codex standards or as decided after subjecting the maximum levels to an appropriate intake assessment method that could be used to verify the compatibility with the JECFA ADI.⁵³

⁵⁰ ALINORM 99/12A, para. 49

⁵¹ Codex Alimentarius Vol. 1A, Section 5.1

⁵² ALINORM 93/12A

⁵³ ALINORM 93/12A, para 33

64. As discussed above (para. 35), for additives assigned a numerical ADI by JECFA, Codex has adopted Annex A to the Preamble of the GSFA as a tool to screen proposed additive use levels based on consideration of their maximum use level and the physiological upper limit to the amount of food and drink that can be consumed each day. Although the Budget Method cannot be used to accurately calculate additive intakes, it is a useful tool for ensuring that an additive's intake does not exceed its ADI. The CCFAC also agreed to forward draft additive maximum use levels for several additives to JECFA for intake assessments.

65. As discussed above (para. 56), for additives assigned JECFA ADIs "Not Specified" or "Not Limited" by JECFA, Codex has adopted GMP maximum use limitations (e.g., Table 3 of the GSFA).

66. The 34th CCFAC established a principle that additives assigned a numerical ADI by JECFA should be assigned numeric maximum use limits in the GSFA.⁵⁴

67. In considering whether to elaborate additional criteria for the endorsement of additive provisions in the GSFA, it is instructive to consider the implications of a Codex food additive maximum level from a food technology perspective and the implications for Codex Member States.

68. The maximum level (ML) of use for an additive is the highest concentration determined to be functionally effective and agreed to be safe by the CCFAC for an additive in a food. It is usually expressed as mg additive/kg of food. The ML usually does not correspond to the optimum, recommended, or typical level of use. The ML is an upper bound of safe use. The optimum level will differ for each application of the additive. It is dependent on the intended technical effect and the specific food, taking into account processing of the food and post-manufacture storage and handling by distributors, retailers, and consumers. Considering that the optimum level of use will differ for each food processed, stored, and handled under various conditions, the ML must be set at a level that is safe yet does not unnecessarily exclude legitimate applications.⁵⁵

69. The MLs in the GSFA are recommendations to Codex Member States for their adoption and consideration when establishing national food safety measures. The GSFA's food additive maximum levels, like all Codex standards, are intended to ensure consumer safety and fair trade practices with respect to foodstuffs in international commerce. Codex standards, in general, provide sovereign states with guidance for crafting and implementing their national legislations, laws, and regulations.

70. To emphasize the last point, it may be preferable not to refer to the additive use levels in the GSFA as maximum permitted levels. This terminology gives the impression that Codex is authorizing or granting permission for additive use up to the specified maximum level. As only sovereign states can authorize, regulate, or grant permissions, the GSFA must be viewed as providing internationally acceptable maximum levels of use of additives in food. These levels are based on levels provided by Codex Member States and those listed in Codex commodity standards and which have been deemed consistent with the safety evaluations of JECFA. Member States may adopt them or not. In this light, the CCFAC may wish to consider amending all references to maximum permissible levels in the GSFA to maximum acceptable levels. This will make it clear that the maximum levels in the GSFA are for guidance and consultation by Codex Member States.

Decisions by CCFAC and CAC; and the Codex Procedural Manual

71. The CCFAC has raised the question of whether the criteria for endorsing food additive maximum use levels in the draft standard need revision. Some delegations have questioned the basis for accepting the

⁵⁴ ALINORM 03/12, para.60.

⁵⁵ France believes that a wording such as " the permitted level " would not be considered as quite different from " the optimum level ". France strongly recommends that all countries may have a further examination of this important issue in the recommendations for discussion.

reported use of an additive by a Member State as prima facie evidence of technological need. These same delegations have questioned whether the principles for resolving questions of technological need may be applicable to the use of additives in foods that, although in international trade, are not widely used.

72. As noted above, since the conceptual beginning of the GSFA, as enumerated in the recommendations of the Denner Paper, the issue of how to translate JECFA ADIs into additive use levels and how to resolve variability of technological need among different Codex Member States has been recognized and considered by Codex in the elaboration of the GSFA.

73. The Commission has taken several actions to address this issue. These include providing a definition of good manufacturing practices,⁵⁶ adopting General Principles for the Use of Food Additives (XOT 01-1972), and incorporating text from both into the Preamble of the GSFA. In addition, section 1.4 of the Preamble (The Permitted Levels of Use for Food Additives of the Preamble) states that:

“The primary objective of establishing permitted levels of use of food additives in various food groups is to ensure that the intake of additives does not exceed the acceptable daily intake. 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 which would verify the compatibility of a proposed maximum level with the ADI. The Danish Budget Method may be used as a first step in this regard.⁵⁷ The submission of actual food consumption data is also encouraged.”

74. The Procedural Manual addresses the issue of food additives in the chapter entitled: “Guidelines for the Acceptance Procedure for Codex Standards.”⁵⁸

“The food additives included in the standard have been assessed and cleared by JECFA. The Commodity Committee and CCFAC have assessed technological need and safety in use.”

75. The Procedural Manual sets forth that commodity committees are to assess the technological need for food additives and CCFAC is to assess their safety in use.

76. In the chapter ‘Relations between Commodity Committees and General Committees’, the Procedural Manual specifies that food additives included in standards elaborated by the commodity committees should be considered to be ‘technologically necessary’.

“Codex Commodity Committees should prepare a section on food additives in each draft commodity standard and this section should contain all the provisions in the standard relating to food additives. The section should include the names of those additives which are considered to be technologically necessary or which are widely permitted for use in the food within maximum levels where appropriate.”

77. Thus, the technological need established by Codex commodity committees is based either on technological factors put forward in support of the application or if the additive is widely permitted for use in the food.

78. As discussed above, the CCFAC has examined various approaches for translating the JECFA ADI into maximum use levels. The committee has agreed on the use of Annex A as a first screen for establishing maximum use levels for additives with numerical ADIs. The committee has also agreed to refer additive uses in the draft standard to JECFA for intake assessments as appropriate.

⁵⁶ Codex Procedural Manual 12th Edition, p. 85

⁵⁷ “Consensus Document on the Danish Budget Method”, Nordic Working Group on Food Toxicology and Risks Evaluation, Report No. 4/90.”

⁵⁸ Codex Procedural Manual, para 16, p. 37, 12th Edition,

79. The CCFAC has had extensive discussions on the issue of technological need (paras. 37-52). As a result of these discussions, the committee agreed on the following principles with respect to its deliberations on technological need.

- Technological need should be addressed through consideration of additive functional classes.
- Recognition that technological need may differ from one country to another.
- Maintenance of a clear distinction between the justification of the level of use and additive intake assessment.
- Approval of a food additive use by a Codex Member State should, in the first instance, be taken as evidence of technological justification and need.

80. The most recent discussion paper on technological justification and need⁵⁹ envisioned that when discussing food additive provisions in the draft standard, the CCFAC would initially focus on the potential for a numerical ADI to be exceeded based on either the application of Annex A or an intake assessment performed by JECFA. If either indicated the potential for the ADI to be exceeded, then a closer examination of the proposed maximum levels would be undertaken. However, CCFAC has not yet documented how it will proceed when JECFA's intake assessments based on the maximum use levels in the draft GSFA, exceed the numerical ADI.

81. The CCFAC has also agreed to several additional principles for establishing maximum use levels in the GSFA. These include the principle that all food additives assigned a numerical ADI by JECFA should be assigned a numerical use limitation.⁶⁰ In addition, the 34th CCFAC discussed whether additives assigned Not Specified or Not Limited ADIs by JECFA should be assigned GMP maximum levels for their provisions in Tables 1 and 2. However, no decision was reached.

Recommendations

82. To address concerns raised, the committee may wish to propose as new work the amendment of the Preamble with a view toward establishing criteria for endorsing food additive maximum use level provisions in the GSFA.

83. Possible amendments to the Preamble include:

- a) Amendment of point 1.1 of the Preamble by including the reference to “additives considered to be technologically necessary or which are widely permitted for use in the food” as set forth in the Procedural Manual.⁷²

For example:

- 1.1 Permitted Food Additives

Only the food additives listed herein are acceptable for use in foods in conformance with the provisions of this standard. Only food additives that have been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and considered to be technologically necessary or that are widely permitted for use in the food and found acceptable for use in foods are included in this standard.

- b) To make clear the criteria that the CCFAC will consider when establishing maximum use levels for additives in the GSFA, a new section of the Preamble (3.5 Principles for the Establishment of Maximum Use Levels in the GSFA) could be added as follows:

⁵⁹ CX/FAC 97/10

⁶⁰ ALINORM 03/12, para. 60

“When establishing maximum levels for the use food additives, the following principles should be applied.

- Additives assigned a numerical ADI by JECFA should be assigned numerical maximum use levels in the GSFA.
 - Additives assigned a non-numerical ADI by JECFA should be assigned GMP use levels in the GSFA.”
- c) To clarify that the additive provisions listed in the GSFA are considered acceptable by Codex and are intended as guidance to Member States, all references to “maximum permissible levels” in the Preamble should be changed to “maximum acceptable levels”. It is the responsibility of Member States to determine whether the use of a specific additive is permitted in foods sold in their country.
- d) Amend the Preamble of the GSFA by clarifying that the establishment of a Codex maximum level is the maximum safe level of use of an additive in a food product within the food category described. In order to be in conformity with the GSFA, the quantity of the additive actually added to food is at or below this maximum level and at the lowest level necessary to achieve its desired technical effect.

84. CCFAC may wish to consider the development of a companion document to the Preamble of the GSFA that describes the operating principles and processes used by CCFAC to elaborate the food additive provisions in the GSFA. The document would show how the general principles in the GSFA Preamble are applied by CCFAC. For example, procedures and principles relating to the inclusion of a food additive in the GSFA, including receiving requests from Member States, criteria for technological justification and the intake assessment process would be appropriate. At the moment, the descriptions of these procedures are contained in several Codex documents. For some issues (e.g., ensuring that maximum levels are likely to result in intakes below the ADI), CCFAC may need to develop, agree to, and document specific procedures.

85. CCFAC may wish to reconsider its procedure for resolving questions of technological need and justification (para. 48) by considering incorporation of the Procedural Manual’s reference to “widely permitted” for use in food. A clearer definition of this term, as used in the Procedural Manual, would be needed. Meeting the criterion of “widely permitted” for use in food could be based on information provided in relevant commodity standards, by the CCFAC’s GSFA working group, or by a select group of technical experts, particularly in those cases where an agreement cannot be reached within CCFAC.

86. The CCFAC may wish to consider endorsing the following procedure for justifying maximum levels of use in the draft GSFA:

Tables 1 and 2 of the GSFA are circulated for comments:

- i) If a Codex Member State considers that a proposed level of use is too high, the Member State will provide data documenting that the proposed level of use presents a risk to public health, leads to consumer deception about the nature of the food, or is technologically unnecessary. If the committee concurs with the concerns raised, then the Member State that initially proposed the level will be requested to present data demonstrating that use of the additive at the proposed level does not present a risk to public health, does not lead to consumer deception about the nature of a food, or is technologically necessary;
- ii) Codex Member State(s) supporting a lower maximum level will be requested to present data demonstrating that the use of the additive at the lower level is sufficient technologically. If a Codex Member State wishes to support a maximum level that has been identified by other Member States as being a risk to public health, technologically unnecessary, or likely to result in consumer deception, the Member State should present data to demonstrate that the proposed maximum level is safe, achieves the desired technological function and that the use of the

additive at the proposed level would not result in consumer deception. Care should be taken that any such debate on risk to public health, technological need, or consumer deception is based on participants dealing with identical or equivalent foods or food classes (i.e., that advocates of a lower level of use are basing their arguments on a similar food/food class as the Member State advocating the higher level).

87. Similarly, an application to increase the maximum use level of an additive in a given food category already appearing in the standard or in the draft standard will not be considered unless information justifying the safety and technological need for the increase is provided. The committee could apply this provision, which already appears in point 7.2 of the Preamble.

88. CCFAC should consider documenting how it will proceed when JECFA's intake assessments, based on food additive provisions in the draft GSFA, predict that the JECFA ADI would likely be exceeded.

IV RELATIONSHIP BETWEEN THE GSFA AND CODEX COMMODITY STANDARDS

Description of Issue

89. The 34th CCFAC considered a discussion paper on the relationship between the GSFA and food additive provisions in Codex commodity standards.⁶¹ The committee agreed that proposals to amend the Preamble with a view toward clarifying the relationship between the GSFA and Codex commodity standards should be developed by a drafting group.⁶²

90. The 34th CCFAC also agreed to the following with regard to the role of Codex commodity committees:

a. When elaborating standards, commodity committees should only consider additives that have been assigned a full ADI by JECFA and have an assigned INS number. The technical effects assigned by the INS (i.e., those described in the list of added functional classes) and technological functions should be used for identifying the food additive use.

b. When elaborating standards, Codex commodity committees should provide the CCFAC with a list of all food additives, including the individual INS number (including any suffixes), within a particular functional class for which the technological need has been justified and may choose to recommend their appropriate maximum levels of use. The CCFAC will incorporate this information in the Draft GSFA for further consideration by the Codex commodity committee.

c. If equivalency between a Codex commodity standard and a single GSFA food category is unavoidable, then the Codex commodity committee should provide the CCFAC with a list of technical effects consistent with those listed in the INS for which technological need has been justified and whose use will not mislead the consumer. The commodity committee, if appropriate, may recommend to the CCFAC levels of use for specific additives that achieve the identified intended technical effects. The CCFAC will incorporate this information in the draft GSFA for further consideration by the Codex commodity committee.⁶³

91. Some delegations attending the 34th CCFAC observed that the differences between the additive provisions for the same product in the GSFA on the one hand, and in the commodity standard concerned on the other hand, stemmed from procedural differences between commodity committees and the CCFAC. If

⁶¹ CX/FAC 02/6

⁶² ALINORM 03/12, para. 50.

⁶³ ALINORM 03/12, para 48

the example of butter is taken, it can be observed that the draft GSFA (March 2002 version of Table 2) lists 110 additives for use in butter and concentrated butter whereas the butter standard lists 8 additives.

92. Therefore, it may be necessary to look closely at the applicable rules and procedures set forth in the various decisions of CCFAC, CAC and in the Procedural Manual and examine 1) the extent to which the Preamble could be amended in order to improve consistency between the GSFA and food additive provisions in Codex commodity standards and 2) the responsibilities of the CCFAC and Codex commodity committees when elaborating food additive provisions in Codex standards.

GSFA

93. One of the earliest decisions by the CAC was that the Codex System should contain, within a single general standard for food additives, provisions for the use of food additives in both standardized and non-standardized foods. As noted above, the CAC shifted the emphasis of its standard-setting activities to horizontal standards from its vertical- or commodity-based approach in 1991, and noted that the general subject committees should examine their terms of reference, while avoiding any delay in the development of horizontal standards.⁶⁴

94. Section 1.2 of the Preamble was endorsed by CCFAC to make clear that the GSFA would cover all foods, standardized or not, and would contain a statement that the food additive provisions of Codex commodity standards shall be included in and superseded by the provisions in the GSFA.⁶⁵

Procedural Manual

95. The terms of reference for the CCFAC include the establishment or endorsement of maximum or guideline levels for individual food additives in foodstuffs and animal feeds.⁶⁶ The terms of reference for the various Codex commodity committees and task forces gives no explicit reference to the establishment of food additive provisions by these committees. In general, the Codex commodity committees and task forces are charged with elaborating worldwide standards, codes of practice, and related texts for commodity-specific foods. Among other Codex Subsidiary Bodies, only the terms of reference for the ad hoc Intergovernmental Task Force on Fruit and Vegetable Juices refers to the relationship between the general subject committees and the commodity committees or task forces. This task force is instructed to give preference to general standards.

96. According to the Procedural Manual, Codex commodity committees should ask the advice and guidance of Codex general subject committees (e.g., CCFAC, Codex Committee on Food Hygiene (CCFH), Codex Committee on Food Labelling (CCFL)) having responsibility for matters applicable to all foods on any points coming within their province. Codex general subject committees may establish general provisions on matters within their terms of reference. The Procedural Manual states that the provisions of Codex general standards (e.g., GSFA, General Standard for the Labelling of Prepackaged Foods), codes or guidelines (e.g., Recommended International Code of Practice - General Principles of Food Hygiene) shall only be incorporated into Codex commodity standards by reference unless there is a need for doing otherwise.⁶⁷ Where Codex commodity committees are of the opinion that the provisions of general standards or codes of practice are not applicable to one or more commodity standards, they may request the general subject committee to endorse deviations from the general provisions. Such requests should be fully justified and supported by available scientific evidence and other relevant information.

⁶⁴ ALINORM 91/40, paras. 61-62.

⁶⁵ ALINORM 93/12A, para 31.

⁶⁶ Codex Procedural Manual, 12th Ed., pp 97-98

⁶⁷ Codex Procedural Manual, 12th Ed., p. 82.

97. Codex has established a standard format for Codex commodity standards.⁶⁸ These include sections on food additives, contaminants, hygiene, labeling, etc. The Procedural Manual also provides additional guidance to commodity committees on the various sections in the standard format.

98. The Procedural Manual⁶⁹ recommends that when elaborating standards, Codex commodity committees should prepare a section on food additives in each draft commodity standard and this section should follow the General Principles for the Use of Food Additives⁷⁰ and the Preamble of the GSFA.⁷¹ The Procedural Manual also states that:

“Codex commodity committees should prepare a section on food additives in each draft commodity standard and this section should contain all the provisions in the standard relating to food additives. The section should include the names of those additives which are considered to be technologically necessary or which are widely permitted for use in the food within maximum levels where appropriate.”⁷²

99. The Procedural Manual⁷³ also states that commodity committees should provide a full explanation to the CCFAC for any departure from the above recommendations. When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by that committee, and forwarded to the CCFAC for endorsement.

Recommendations

100. The CCFAC may wish to:

- Propose that the CCFAC begin as new work the amendment of the Preamble of the GSFA by including a new section on the Relationship between the GSFA and Codex commodity standards.

1.2 Foods in Which Additives May Be Used

This standard sets forth the conditions under which 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 standard and 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 might also be taken into account when considering food additive provisions in similar non-standardized foods.

- Propose that the CCFAC begin, as new work, revisions in the Procedural Manual of the Food Additives Section in the Format for Codex commodity standards⁷⁴ and Food Additives section on the Relations Between Commodity Committees and General Committees.⁷⁵
- The food additives section in the Format of Codex commodity standards could be replaced with the following:

⁶⁸ Codex Procedural Manual, 12th Ed., pp. 78-81.

⁶⁹ Codex Procedural Manual, 12th Ed, p. 82.

⁷⁰ Codex Alimentarius Commission Vol. 1A.; XOTO1 - 1972.

⁷¹ CODEX STAN 192-1995 (Rev. 2-1999).

⁷² Codex Procedural Manual, 12th Ed., p. 82.

⁷³ Codex Procedural Manual, 12th Ed., p. 85.

⁷⁴ Codex Procedural Manual, 12th Edition (2002), p. 79

⁷⁵ Codex Procedural Manual, 12th Edition (2002), p. 84

Food Additives

This section should be prepared in accordance with the General Principles for the Use of Food Additives and the Preamble of the General Standard for Food Additives. It should refer to the Codex General Standard on Food Additives by citing the appropriate food category in the General Standard and may take the following form:

“The food additive provisions listed in food category [followed by the General Standard’s food category number and title] of the Codex General Standard for Food Additives (CODEX STAN 192-1995) may be applied.”

If appropriate, the commodity standard may also identify the food additive classes described in the Codex International Numbering System for Food Additives (XOT 04-1999) that are technologically needed.

- The Food Additives and Contaminants Section on the Relationship Between Codex Commodity Committees and General Committees should be replaced with the text in Annex II.
- Propose that the CCFAC consider preparing a discussion paper that reviews the food additive provisions in the GSFA and Codex commodity standards. In cases where the Codex commodity is very similar or identical to a food category or sub-category in the GSFA’s food category system (e.g., infant formula (13.1), margarine (2.2.1.2) fruit juice (14.1.2.1) sugar (11.1), butter (2.2.1.1)), this discussion paper should propose options for resolving apparent inconsistencies.

Annex I**Origins and Scope of the Codex General Standard for Food Additives**

1. Prior to 1991, the standard-setting activity of the Codex Alimentarius Commission (CAC) focused on the development of commodity or so-called 'vertical' standards (e.g. Canned Plums [Codex Standard 59-1981], Wheat Flour [Codex Standard 152-1985]). Codex commodity standards typically have provisions for labelling, the use of food additives, maximum residue levels for pesticides and veterinary drugs, and maximum levels for contaminants.
2. The question of whether the CCFAC should provide 'opinions' on the use of food additives other than those included in Codex commodity standards was initially raised by the Codex Secretariat during the 18th Session of the committee (1985).⁷⁶ Dr. G.O. Kermode also highlighted the absence of provisions for the use of additives in non-standardized foods in a report to the Codex Executive Committee in 1986⁷⁷ and he expressed concern about the status and future direction of Codex.
3. At its 19th Session (1987), the committee discussed a paper⁷⁸ prepared by the Codex Secretariat and the Netherlands that suggested procedures for providing for additive uses in foods for which no Codex standards exist. The committee supported the views expressed by the U.S. Delegation that there were many difficulties in initiating an exercise to establish provisions for the safe use of additives in non-standardized foods. Most notable was the need for a consensus on the list of food additive uses. While Codex Member States may have their individual lists, the combined list would consist of numerous and different food types in which each additive could be used. Obtaining a consensus on the technological need for all such uses would be difficult because of differences in regional and cultural dietary habits, and regional public health measures. Moreover, procedures to evaluate the cumulative intake of an additive based on a long list of additive uses were unavailable and would have to be developed.⁷⁹
4. At its 20th Session (1988),⁸⁰ the Codex Secretariat presented a paper to the committee outlining two approaches for maintaining the up-to-date status of food additive provisions in Codex standards: (i) continue to review additive provisions on a case-by-case basis, or (ii) develop general provisions for the use of additives. The committee recognized that the second approach could be extended, at least in principle, to non-standardized foods. Many Delegations expressed concern that the second approach would lead to inadequate control of food additive use and that the standard might include the use of a number of additives without consideration of their technological need. The CCFAC agreed "that a consultant should prepare a paper on the future activities of the CCFAC in regard to the establishment and regular review of provisions relating to food additives in Codex standards, and the possible mechanism for establishment of general provisions for the use of food additives in non-standardized foods as a horizontal approach in light of changing requirements in international trade".⁸¹

The Denner Paper

5. The "Denner Paper"⁸² was prepared in response to the 20th CCFAC's recommendation and was discussed by the 21st CCFAC (1989). The following ten recommendations to CCFAC, FAO, WHO, JECFA, and Codex Member States contain the essence of the Denner paper.

⁷⁶ CX/FA 85/16

⁷⁷ CX/EXEC 86/33/CRD 1

⁷⁸ CX/FA 87/19-Add.1

⁷⁹ ALINORM 89/12A, paras. 268-269

⁸⁰ CX/FA 88/10-Part 1

⁸¹ ALINORM 89/12

⁸² CX/FA 89/16

Recommendation 1

FAO should arrange for the Commission at its next Session to consider the future of the Codex Food Standards Programme in respect of compositional food standards taking into account:

- (i) Changing attitudes towards compositional food standards
- (ii) Changing food technology
- (iii) Changing consumer expectations

It may be that a special conference should be convened to allow a more wide-ranging debate outside the constraints of a formal Commission Session.

Recommendation 2

All member nations should give comprehensive and constructive responses to requests for comments from FAO. Codex will serve member nations best if FAO is in a position to understand fully the various national positions. It is particularly important to identify changes in national food policy or shifts in government thinking so that FAO can plan ahead accordingly.

Recommendation 3

Member nations should agree to accept the safety evaluations of JECFA.

Recommendation 4

Negotiations with member nations should be initiated with a view to obtaining additional resources for a considerable expansion of the role of JECFA and a major acceleration in the rate of safety evaluations made by the committee each year.

Recommendation 5

CCFAC should consider in the light of "principles for the safety assessment of food additives and contaminants in food" whether it has sufficient information from JECFA on how to translate ADIs into levels of use in food and drink. If so, then it should produce clear guidelines so that all member nations will understand what factors are, and are not, included in the overall safety factor to ensure, for example, that everyone takes account of special groups in the population (especially children) in the same way. If CCFAC requires further assistance from JECFA then a comprehensive list of clear direct questions should be prepared and forwarded to JECFA.

Recommendation 6

Continuing efforts should be made to ensure that JECFA reports and monographs are as helpful as possible to users of ADIs. JECFA monographs should continue to explain precisely how the ADI was derived from the toxicological data. It is particularly important to set out in each case the quantitative value of each individual factor contributing to the overall safety factor used to convert the "no effect level" to the ADI. When it is not possible to allocate an ADI to a particular additive, every effort should be made to establish whether or not particular levels in particular food can be at least provisionally endorsed.

Recommendation 7

In the interests of free trade there should be greater recognition of, and tolerance shown towards, the variability of technological need among different nations and also with time. There should be a corresponding decrease in government prohibitions on additives in individual foods and a greater

reliance on informative labelling so that consumers can choose for themselves which type of product they wish to buy.

Recommendation 8

CCFAC can never properly carry out its function of endorsing food additive usage in individual foods unless it considers additive usage in all foods. CCFAC should formally take on this task to enable it to serve Codex more effectively. In consequence, the Codex Alimentarius Chapter on Food Additives requires a major revision including a complete restructuring to accommodate provisions for non-standardized foods.

Recommendation 9

CCFAC needs to be absolutely certain of the implications of JECFA evaluations in order to translate these into levels of use in individual foods. Doubts exist in particular in relation to certain groups of closely related compounds which have been allocated the same numerical ADI but do not appear to have been formally assigned to a group ADI. In theory such compounds could, therefore, each be used in the same food up to the limit of the individual ADIs rather than to the limit of the collective ADI. The Secretariat should clarify, seeking advice as necessary from JECFA, so that CCFAC has an unequivocal data base on which to base its work.

Recommendation 10

The CCFAC should adopt the following work plan:

- (i) Agree to prepare a new Codex standard for Food Additives along the lines proposed (par. 39-40 and Appendix III of CX/FAC 89/16)
- (ii) Set up three working parties to deal with different classes of additives to begin work, as a first priority, with additives with an ADI of 10 or less (par. 41-46 of CX/FAC 89/16)
- (iii) Collect usage and intake data for additives with an ADI of 10 or less and, where necessary, prepare a list of restrictions on use taking proper account of technological need and national "styles" of product (paras. 47-51 and 55 of CX/FAC 89/16)
- (iv) Redraft the food additive provisions of existing commodity standards to cross-refer to the new standard for food additives (par. 52-54 of CX/FAC 89/16)
- (v) As an interim measure, allow the "low priority" additives to be used subject only to GMP, except in those foods from which they would be totally excluded (par. 56 of CX/FAC 89/16).

6. The 21st CCFAC⁸³ (1989) endorsed Recommendations 6 and 9 regarding the importance of JECFA monographs and the translation of JECFA ADIs into levels of use. The committee also agreed to discuss further Recommendations 5, 8, and 10 at its next session.

7. The 18th CAC⁸⁴ (1989) unanimously supported the convening of an international food standards conference as contained in Recommendation 1 of the Denner Paper.

8. The 22nd CCFAC⁸⁵ (1990) endorsed Recommendation 5, which addressed the need for clear risk communication between JECFA and CCFAC. With respect to Recommendations 8 and 10, the CCFAC agreed to limit, for the time being, its efforts to develop a general standard for food additives to only those additives that have been evaluated by JECFA.⁸⁶ The CCFAC also agreed that, in developing a general

⁸³ ALINORM 89/12A, para. 26

⁸⁴ ALINORM 89/40, para. 315

⁸⁵ ALINORM 91/12, para. 30

⁸⁶ ALINORM 91/12, paras. 31-37

standard, priority should not be given to any particular group of additives, or to additives with a low ADI, as it was more important to consider the ADI within the context of potential intake. Several Delegations expressed concerns about the complexity of developing a general standard for food additives, especially the need for assessing additive intake on a worldwide basis, and the national nature of many of the non-standardized foods. Attention was also drawn to the need for categories of non-standardized foods. As a starting point, the CCFAC requested the Secretariat to prepare a report on antioxidants and preservatives by grouping together the current Codex uses for these additives in the format proposed in the Denner Report.

9. The 23rd CCFAC (1991)⁸⁷ considered government comments to the Codex Secretariat's report on antioxidants and preservatives⁸⁸ based on food additive provisions derived from Codex commodity standards. The committee decided that this information provided an excellent basis for continued work on the general standard. To facilitate the development of a general standard for the use of additives, the CCFAC established an ad hoc Working Group (GSFA WG) with the United States serving as Chair. The CCFAC agreed to the following terms of reference for the GSFA WG, in addition to the recommendations from the Denner Paper:

- Establish general principles for the GSFA, including a discussion of its proposed format and scope.
- Elaborate a GSFA that includes all foods and which initially should be restricted to antioxidants and preservatives.

10. The 23rd CCFAC established a drafting group⁸⁹ to prepare: a) General Principles for the GSFA; and b) a proposed draft GSFA for antioxidants and preservatives in time for discussion by the 24th CCFAC.

The FAO/WHO and GATT Conference on Food Standards, Chemicals in Food and Food Trade

11. In March 1991, the FAO/WHO and GATT Conference on Food Standards, Chemicals in Foods and Food Trade was held to review aspects of the work and procedures of Codex, and import and export controls which impeded international trade in food.⁹⁰ The conference recommended that Codex strengthen the horizontal work of its general subject committees (e.g., CCFAC) so that matters of general importance, such as labeling, additives, contaminants, and methods of analysis and sampling, would be handled entirely by the appropriate general subject committee. The general subject committees would provide the main source of direction in their area of expertise and would be independent of proposals or provisions forwarded by Codex commodity committees. This was seen as necessary if Codex standards were to encompass all foods moving in international trade and to provide general guidance and recommendations to promote safe food handling and processing.

12. In response to this conference, the 19th Session of the Codex Alimentarius Commission (CAC) (1991), welcomed the recommendation to strengthen its horizontal approach to its standard setting activities. The CAC noted that the general subject committees should examine their terms of reference in this regard, but did not want this to delay the development of horizontal standards.⁹¹ The 19th CAC also agreed that Codex commodity standards should be revised in a manner consistent with the recommendations of the Denner Paper and the 1991 FAO/WHO Conference with a view toward simplification and a primary emphasis on protection of consumer health and the safety of foods.⁹² The Procedural Manual was subsequently amended to provide the following guidance to Codex commodity committees with respect to the food additive sections of their standards:

⁸⁷ ALINORM 91/40, paras. 30-37

⁸⁸ CL 1990/26-FAC

⁸⁹ Australia, Belgium, Canada, Denmark, Finland, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, Switzerland, Thailand, United Kingdom, United States of America, EEC, IOCU, IFAC, ILSI, IDF, CIAA, and IFGMA.

⁹⁰ Report of the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade in Cooperation with GATT, 1991 Rome

⁹¹ ALINORM 91/40, paras. 61-62

⁹² ALINORM 91/40, paras. 95-97 and ALINORM 91/30; para 24

"When establishing provisions for food additives, Codex committees should follow the General Principles for the Use of Food Additives and the Preamble for the General Standard for Food Additives. Full explanation should be provided for any departure from the above recommendations.

When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the Codex Committee on Food Additives and Contaminants for endorsement. When the Codex Committee on Food Additives and Contaminants decides not to endorse specific additive provisions (use of the additive, or level in the end-product), the reason should be clearly stated. The section under consideration should be referred back to the committee concerned if further information is needed, or for information if the Codex Committee on Food Additives and Contaminants decides to amend the provision.

When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions, should be forwarded directly by member countries to the Codex Committee on Food Additives and Contaminants."⁹³

13. The 19th CAC also agreed: (i) to support the CCFAC's establishment of the GSFA WG under the chair of the United States; and (ii) that the CCFAC should prepare a Proposed Draft GSFA based on the Denner Paper and the terms of reference for the GSFA WG⁹⁴ for circulation and comment at Step 3.

⁹³ Codex Alimentarius Procedural Manual, 12th ed., pp. 84-85.

⁹⁴ ALINORM 91/40, para. 213

Annex II**Proposed Revision to the Procedural Manual****FOOD ADDITIVES AND CONTAMINANTS⁹⁵**

Codex commodity committees should prepare a section on food additives in each draft commodity standard. The food additive section of Codex commodity standards should reference the Codex General Standard for Food Additives (CODEX STAN 192-1995). Exemptions from, or additions to, the General Standard that are necessary for its interpretation in respect of the product concerned should be justified fully and should be restricted as much as possible. Information specified in each Codex commodity standard should normally be limited to the following:

- A statement that the food additives may be used in accordance with the Codex General Standard for Food Additives (CODEX STAN 192-1995).
- The title and number of the relevant food category in the Codex General Standard for Food Additives.

The commodity standard may state the relevant food additive classes as described in the Codex International Numbering System for Food Additives (XOT 04-1999) that are technologically needed in the standardized food. Commodity committees may also prepare a working paper for the Codex Committee on Food Additives and Contaminants with a list of food additives and their maximum use levels necessary to achieve a particular technical effect in foods subject to the commodity standard. The commodity committees are responsible for justifying the technological need for every additive provision in standards elaborated under their terms of reference.

Good Manufacturing Practices means that:

- the quantity of the additive added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food;
- the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technological effect in the food itself, is reduced to the extent reasonably possible;
- the additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient. Food grade quality is achieved by compliance with the specifications as a whole and not merely with individual criteria in terms of safety.

All provisions in respect of food additives (including processing aids) and contaminants contained in Codex commodity standards should be referred to the Codex Committee on Food Additives and Contaminants preferably after the Standards have been advanced to Step 5 of the Procedure for the Elaboration of Codex Standards or before they are considered by the Commodity Committee concerned at Step 7; ~~though~~ such reference should not be allowed to delay the progress of the Standard to the subsequent Steps of the Procedure.

All provisions in respect of food additives will require endorsement by the Codex Committee on Food Additives and Contaminants. Endorsement should be based on the ~~basis of~~ technological justification submitted by the commodity committees, or the recommendations of the Joint FAO/WHO Expert Committee on Food Additives concerning the safety-in-use (acceptable daily intake (ADI) and other restrictions) and

⁹⁵ Codex Alimentarius Procedural Manual, 12th ed., pp. 84-85. Proposed revisions are indicated in bold font; deletions by strike out.

estimates of the potential and, where possible, the actual intakes of the food additives, thus ensuring conformity with the General Principles for the Use of Food Additives.

In preparing working papers for the Codex Committee on Food Additives, the Secretariat should make a report to the Committee concerning the endorsement of provisions for food additives (including processing aids), on the basis of the General Principles for the Use of Food Additives. Food additive provisions should indicate the International Numbering System (INS) number, the ADI, technological justification, proposed level, and whether the additive was previously endorsed (or temporarily endorsed).

When commodity standards are sent to governments for comment at Step 3, they should contain a statement that the provisions “in respect of food additives and contaminants are subject to endorsement by the Codex Committee on Food Additives and Contaminants and to incorporation into the General Standard for Food Additives or the General Standard for Contaminants and Toxins in Foods.”

When establishing provisions for food additives, Codex committees should follow the General Principles for the Use of Food Additives and the Preamble of the General Standard for Food Additives. Full explanation should be provided for any departure from the above recommendations.

When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the Codex Committee on Food Additives and Contaminants for endorsement. When the Codex Committee on Food Additives and Contaminants decides not to endorse specific additives provisions (use of the additive, or level in the end-product), the reason should be clearly stated. The section under consideration should be referred back to the Committee concerned if further information is needed, or for information if the Codex Committee on Food Additives and Contaminants decides to amend the provision.

When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions should be forwarded directly by member countries to the Codex Committee on Food Additives and Contaminants.