codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7 B **CX/FAC 03/06 - Add. 1**
February 2003

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-fifth Session
Arusha, United Republic of Tanzania, 17 - 21 March 2003

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

COMMENTS

The following comments have been received from USA, EUROPEAN COMMUNITY, IFU, ISDC, IFAC:

USA:

The United States appreciates the opportunity to provide the following comments for consideration by the Codex Committee on Food Additives and Contaminants (CCFAC) for CX/FAC 03/06, on the Proposed Draft Revised Preamble to the Codex General Standard for Food Additives (GSFA) for consideration by the 35th Session of the CCFAC.

General Comments
The U.S. recognizes that the establishment of safe conditions of use for food additives can be beneficial to consumers in a number of ways. For example, food additives can preserve nutritional quality, prolong durability, improve the taste and texture, and ensure the safety of food.

The U.S. reaffirms its support for the following decisions on the principles for the elaboration of the GSFA.

1. The U.S. strongly supports the Committee's emphasis on establishing safe levels of use for food additives. The Committee's reliance on the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for safety assessments is consistent with the Commission's decision to base Codex standard-setting activities on science-based risk assessments. Moreover, the Committee's reliance on a Member State's evaluation of the safety of specific additive provisions provides an additional level of confidence in the safety of the additive provisions under consideration. The CCFAC has also relied on the use of Annex A to the Preamble of the GSFA and utilized JECFA's expertise on exposure assessments to evaluate the safety of proposed levels of use, as appropriate. This four-tiered approached is a pragmatic, science-based approach that has served the CCFAC well.

2. The U.S. reaffirms its support for the decision by the 19th Session of the Codex Alimentarius Commission to review and revise all Codex standards with a view toward their simplification and their primary emphasis on the protection of consumer health, food safety, fair trade practices, and protection against fraud.

3. The U.S. reaffirms its support for the Commission's decision to elaborate a GSFA based on the principles described in the Denner Paper.

4. The U.S. reaffirms its support for the Commission's decision to elaborate a GSFA that covers all food traded internationally, including those conforming to Codex commodity standards.

5. The U.S. reaffirms its support for the elaboration of a GSFA that ensures food safety while being no more trade restrictive than necessary. In this regard, we support the committee's approach to utilize the maximum use levels proposed by Member States and specified in Codex commodity standards in the draft standard, followed by evaluation and full discussion by the CCFAC and its *ad hoc* GSFA Working Group. In our view, this is a practical means for ensuring that the final GSFA protects consumer health and ensures fair trade practices.

6. The U.S. reaffirms its support for the CCFAC's decision to recognize Member State's reported use of an additive as *prima facia* justification for the technological need for the use of an additive. We also support the principles for resolving questions of technological need established during the 30th CCFAC (ALINORM 99/12, para.47).

7. The U.S. reaffirms its support for the CCFAC's decision to focus its discussion of the technological need for the use of additives on additive functional classes and not on individual additives.

8. The U.S. reaffirms its support of the Preamble to the GSFA, especially the obligations in the Preamble, that in order to be in conformance with the GSFA, all food additives, regardless of the maximum use level listed in the GSFA tables: 1) must be used under good manufacturing practices (GMP) conditions, and 2) must not be used in a manner that misleads consumers. The GSFA's GMP requirements apply to all provisions in the GSFA, independent of whether there is a GMP or a numerical maximum use level. This means that, regardless of the maximum use level adopted by Codex, the GSFA sanctions the use of additives only at the minimum level necessary to achieve their intended technical effect. This is important, because the responsibility for establishing additive use levels that meet a specified level of public health protection and that do not mislead consumers remains under the ultimate authority of each Member State. This approach is necessary to accommodate differing technological needs and food consumption patterns among Codex Member States and to ensure that the GSFA maximizes food safety, while ensuring that the GSFA is no more trade restrictive than necessary.

Criteria for Establishing Food Additive Provisions

In general, the U.S. supports amending the Preamble of the GSFA to clarify the criteria for establishing food additive maximum use levels in the standard.

Recommendation 1

The U.S. does not support the proposal to amend section 1.1 of the Preamble to include a 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 (page 84, 12th ed.) (See CX/FAC 03/06 para. 83(a)). We believe that this amendment is counter to the Commission's charge to the CCFAC to develop a general standard consistent with the Denner Paper. Moreover, the reference to the Procedural Manual refers to text that is intended as guidance to Codex commodity committees. This text predates the decision by the Commission to begin work on the GSFA and reflects obsolete practices of the Commission. When the Commission endorsed the elaboration of the GSFA and other general standards as new work, it recognized that it had created inconsistencies in the Procedural Manual, but agreed that the elaboration of general standards and the revision of Codex commodity standards should not be delayed by attempts to first resolve the inconsistencies. Furthermore, the general provisions of the Preamble make clear that the amount of an additive used is only justified at the minimum level necessary to achieve the intended technical effect. If the

intended technical effect is not needed in the food, no basis exists for justifying the introduction of the additive into that food; and such introduction would not conform to the GSFA. In many instances, the recognition of a technological need for an additive in a food varies greatly among Codex Member States. For this reason, the addition of the proposed text can only lead to contentious debates in the CCFAC that will divert its focus from elaborating a general standard that protects consumers' health and ensures fair trade practices.

Rather than amending section 1.1 of the Preamble to the GSFA as proposed, the United States recommends that the referenced section of the Procedural Manual be revised to reflect the current focus of the Codex Commission on the development of science-based standards that protect consumer health and ensure fair trade practices.

Recommendation 2

The U.S. has concerns regarding the recommendation to amend section 1.1 of the Preamble to require that additives assigned numerical JECFA ADIs must be assigned numerical maximum use levels (see CX/FAC 03/06 para. 83(b)). In principle, this is a reasonable first approach; however, the Committee must be pragmatic in its application. As noted in our comment responding to CL 2002/44-FAC, in some circumstances there are valid technical justifications based on the inherent properties of the additive or its intended conditions of use where it is either impractical or unnecessary to establish numerical maximum use levels to ensure safe conditions of use. We offer the following two examples to illustrate circumstances in which a pragmatic approach is recommended.

The first example involves the endorsement of maximum use levels for caramel colors III and IV (INS Nos. 150c and 150d). The 31st CCFAC made an explicit exception to this principle when it specifically endorsed GMP limitations for the use of caramel colors III and IV (ALINORM 99/12A, para. 42). This decision was based in part on the absence of requirements for the color intensity or content of the active coloring principle in the Codex specifications for the identity and purity for caramel colors III and IV and the variation in the amount of the active coloring principle in different preparations of these colors (See CX/FAC 99/6 Add. 1, comment from the Delegation of Japan). Therefore, in the absence of an identified safety concern, the Committee used a pragmatic approach and agreed that establishing numeric maximum levels for these two colors was unnecessary for ensuring the safety of consumers and impractical from a food technology standpoint because the level of caramel III or IV necessary to achieve the intended coloring effect depended in large part on the amount of coloring principle in each preparation of the color.

A second example involves the use of high intensity sweeteners. When considering the use of these sweeteners (e.g., acesulfame potassium (INS No. 950), aspartame (INS No. 951), sucralose (INS No. 956)), technological considerations limit the amount of the high intensity sweetener that can be added to foods should be taken into account. The GSFA food category system applies to all foods as marketed. Most of the food categories refer to finished foods that are consumed directly. However, tabletop sweeteners (food category 11.6) are not consumed directly. Rather, consumers use tabletop sweeteners by either sprinkling them onto or mixing them into foods and beverages, and they do so according to their own taste. Moreover, tabletop sweeteners are sold to the consumer in powder (packets and bulk), liquid and tablet form. Importantly, the use of high intensity sweeteners is technologically self-limiting. That is, adding too much of a tabletop sweetener results in a food or beverage that is unacceptably sweet or that has an unappealing flavor. As an outcome of this self-limiting effect, the level of consumption of any high intensity sweetener is limited.

Moreover, because of the highly intense sweetening effects of these substances (180 - 2000 times sweeter than sugar), only small quantities of tabletop sweetener are needed to achieve the desired level of sweetness for a food or beverage. For sucralose, which is approximately 600 times sweeter than sugar, tabletop formulations in packet and granular form contain only about 1% sucralose; bulking agents makes up the rest of the tabletop formulation. Thus, a half-gram serving of either the packet or granular formulation, equal in sweetness to one teaspoon of sugar, consists of about 5 milligrams of sucralose, which is about 83

micrograms of sucralose/kilogram of bodyweight for a 60 kilogram individual. JECFA has assigned sucralose an Acceptable Daily Intake (ADI) of 15 mg/kg bw/p/d.

When estimating daily intakes of high intensity sweeteners, even with highly conservative approaches based on the assumption that a single high intensity sweetener replaces all added sugar in the diet, it is generally not surprising to find that the resulting intake estimates are well below the ADI. An example of this is borne out by examination of actual post-marketing surveillance data for aspartame. Studies done in Canada, the U.S. and Brazil have shown that aspartame consumption is only a fraction of the Estimated Daily Intake (EDI) that, in turn, is less than the ADI for aspartame.

In sum, the United States generally supports the principle endorsed by the 34th CCFAC; however, we recommend that the CCFAC apply the principle pragmatically. If the Preamble is amended as proposed, we recommend that the following additional language be included to clarify that this is a principle and not a requirement.

> "When establishing maximum levels for the use of food additives, **it is desirable, although not required that** 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."

Recommendation 3

The U.S. supports the recommendation to replace all references to "maximum permissible levels" or "permitted levels" in the Preamble to "maximum acceptable levels" or "acceptable levels" (see CX/FAC 03/06 para. 83(c)). We believe that this is an important change to clarify that the food additive provisions in the GSFA are acceptable for use in foods traded internationally. Moreover, Codex is not responsible for "approving" or "permitting" practices and procedures for food production. Rather, Codex is responsible for elaborating standards and codes of practice that provide guidance for Member States to consider when establishing their national food safety measures.

Recommendation 4

The U.S. supports amending the Preamble to the GSFA to clarify 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 (See CX/FAC para. 83(d)). In order to be in conformity with the GSFA, the quantity of the additive actually added to food must be at or below this maximum level and at the minimum level necessary to achieve its desired technical effect. We propose the addition of the following text to section 2 (Definitions) as a new paragraph 2(d) of the Preamble:

> "**The acceptable maximum level** of use of an additive established in this standard is the highest concentration determined to be functionally effective and agreed to be safe by the Codex Alimentarius Commission. The acceptable maximum level is usually expressed as mg additive/kg of food. The acceptable maximum level usually does not correspond to the optimum, recommended, or typical level of use. The acceptable maximum level is an upper bound of safe use. The optimum use level will differ for each application of the additive. The optimum level 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. Food manufacturers should strive to use the optimum level of use (i.e., the minimum amount necessary to achieve the intended technical effect) based on how each food is processed, stored, and handled under various conditions."

Recommendation 5

The U.S. supports 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 (see CX/FAC 03/6, para. 84). The development of this companion should reflect the decisions of the Commission and the CCFAC. The following documents and text would form a good basis for the development of such a companion document: CX/FAC 03/6, CX/FAC 03/7, and CX/FAC 97/7.

Recommendation 6

The U.S. prefers the procedure agreed to by the 30th CCFAC for resolving questions of the technological need for the use of an additive (See ALINORM 99/12, paras. 47-48) to the proposal in the discussion paper (CX/FAC 03/06, para. 86). The current procedure recognizes a Member State's reporting of a food additive use as *prima facia* evidence of technological need. This is an important principle to further the Commission's charge to CCFAC to develop a general standard that:

> "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." (Denner Paper, Recommendation 7, CX/FA 89/16)

Moreover, the current procedures have the advantage of being a tiered approach and also provide guidance to the Committee on how it should proceed when questions of technological need are raised. In addition, the current procedure provides a sound basis for requiring that challenges to proposed maximum levels, as well as responses to challenges, be fully documented and science-based.

Relationship Between the GSFA and Codex Commodity Standards

Recommendation 1

The U.S. supports the recommendation to revise section 1.2 to the Preamble of the GSFA (CX/FAC 03/6, para. 100 (first bullet)) to clarify the relationship between the food additive provisions in the GSFA and in Codex commodity standards.

Recommendation 2

The U.S. supports the recommendation (CX/FAC 03/6 para, 100 (second bullet)) that the CCFAC propose as new work the revision of the following sections of the Procedural Manual:

> 1) Food additives in the chapter on the format for Codex commodity standards; and
> 2) Food additives and contaminants in the chapter on relations between commodity committees and general committees.

The U.S. supports the proposed text for revising the food additives section of the chapter in the Procedural Manual on the format for Codex commodity standards (CX/FAC 03/6 100 (third bullet)).

Recommendation 3

The U.S. does not support the recommendation to prepare a discussion paper that reviews the food additive provisions in the GSFA and Codex commodity standards (CX/FAC 03/6 100 (fifth bullet)). In our view, such a paper is unnecessary. The 34th CCFAC agreed to guidance regarding the roles of the Secretariat, commodity committees, and the CCFAC (ALINORM 03/12, paras. 47-49). Moreover, the information that would be contained in such a discussion paper is readily available by consulting Annex C to the Preamble (cross reference of the food category system and Codex commodity standards) and the commodity standards, and comparing this information to the GSFA Tables. Finally, preparation of such a discussion paper will provide no new information to the CCFAC's *ad hoc* GSFA Working Group, as information on relevant food additive provisions in Codex commodity standard is made available when the working group discusses specific provisions in the draft GSFA. The United States is concerned that the addition of such a discussion paper will only add an additional item to the CCFAC's agenda and will detract from its ability to make progress on the elaboration of the GSFA.

Recommendation 4

The U.S. supports the inclusion of the proposed revision the chapter in the Procedural Manual on relations between commodity committees and general committees (CX/FAC 03/6 para. 100, fourth bullet) and Annex II).

EUROPEAN COMMUNITY:

1. The European Community would like to congratulate the drafting group and its leaders, France and the United States of America, on the excellent discussion paper that goes through the history of the development of the General Standard on Food Additives (GSFA) and sets out the current issues that need to be addressed in order to ensure the elaboration and functioning of this standard.
2. The European Community would like to make the following remarks on this discussion paper.

Part III

Criteria for establishing food additive provisions

Introduction

3. In the introduction (para 60) the question is raised whether the reporting by a Member State of the use of an additive should be regarded as prima facia evidence of the technological need for the use of an additive.
4. In principle, the EC could agree with this conclusion. In practice, however, it has already been noticed that even if the legislation of a Member State provides for the use, it does not prove that the food industry would use the additive in the application in question, and, therefore, may not need the provision. This may be due to approach taken when legislation has been laid down.
5. Therefore, a Member State supporting an inclusion of additive provision in the GSFA should not only do it on the basis that the provision is contained in the national legislation, but also after verifying with the food industry that the additive is actually used for this purpose and that the food in which it is used is traded internationally.
6. In the Codex General Principles for the Use of Food Additives (para 61b) it is stated that "Approval or temporary approval for the inclusion of a food additive in an advisory list or in a food standard should be at the lowest level of use necessary to achieve the desired effect."

7. In line with this principle, the European Community suggests that, instead of automatically adopting the highest reported use level of each additive as the maximum use level, the lowest reported use level should be adopted by the CCFAC.

8. In para 68, the maximum level of use is described as "an upper bound of safe use". The EC agrees that this should be the objective when setting the levels of use. However, for additives with numerical ADIs, it would require taking into account the intake from all proposed uses, not only from the one food or food category where the maximum level is set. Therefore, one single use level of the additive in one category doesn't guarantee the overall safe use of the additive. On the other hand, to set the maximum level on the basis of toxicological safety may well exceed the technologically needed level of the additive. In any case, in elaborating the GSFA more attention must be paid to overall proposed uses and use levels of an additive.

Recommendations

9. The EC agrees with the suggested amendment to Preamble as laid down in para 83 a and b.

10. The EC agrees with the suggestion to change the wording "permitted maximum levels" to "acceptable maximum level" in order to clarify and emphasise that the maximum levels in the GSFA are for guidance and consultation by Codex Member States (para 83c). As "acceptable maximum level" however indicates that a higher level of use could be unacceptable, it guides the user to use the amount indicated or less in the application.

11. The EC does not entirely agree with the proposed amendment to Preamble as described in para 83d (see point 8 above).

12. The EC agrees with the recommendation to develop guidelines that describe the operating principles and process to elaborate food additive provisions (para 84). This would enable the petitioner (Member State) to provide from the start sufficient information on the proposed use for CCFAC facilitating the decision making process.

13. The EC supports the recommendation that, like for commodity standards, the food additive provisions incorporated in the GSFA should reflect widely permitted use (para 85). This would establish that international trade would be likely to occur for the (non-standardised) food product in question.

14. The EC does not agree with the recommendation to endorse the procedure for justifying maximum levels of use in the draft GSFA as described in para 86. The burden of proof is laid down on the Member State that objects to a particular dose or use. This is in conflict with the principles governing the authorisation of additives, as it should be the party applying for authorisation for a new use that must provide proof that the application is justified.

15. Therefore, the EC suggests that paragraph 86 is replaced by the following:

    "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) The lowest reported level of use is taken as the starting point for discussion.

    ii) If a Codex Member State considers that a proposed level of use is too low, the Member State will provide data documenting that the proposed level of use is technologically insufficient and that a higher proposed level of use would not present a risk to public health and would not lead to consumer deception about the nature of a food. Care should be taken that any debate on risk to public health, technological need, or consumer deception is based on participants dealing with identical or equivalent foods or food classes."

16. The proposal above is in line with what is said in para 87.

17. The EC agrees that CCFAC should clarify how will it proceed if the intake assessment done by JECFA indicated that the ADI would be exceeded.

Part IV

Relationship between the GSFA and Codex Commodity Standards

Recommendations

18. The European Community can agree with the most of the recommendations in para 100.
19. However, on the format of Codex commodity standard it is proposed that in the standard reference would be made to the food additive provisions of the corresponding food category of the GSFA and that food additive classes could be described. No mention is made of the possibility that the commodity committee would like to agree on the use of specific additives. This possibility is however, mentioned in the Procedural Manual (see Annex II).
20. The recommendation would simplify the commodity standard, but currently in commodity standards in addition to functional classes, individual food additives are also listed. Not all food additives within the same functional class have the same effect in the same food. For example, efficacy of sorbates and benzoates, both preservatives, depends on the pH of the food matrix. It should also be noted that sulphites fall under many functional classes (acidity regulator, antioxidant, bleaching agent, flour treatment agent, firming agent, preservative, sequestrant, stabiliser). Sulphites shouldn't be allowed in all foods that need, for example, acidity regulators. Therefore, it seems justified, at least for certain functional classes, that the commodity standard lists the additives that really achieve the necessary effect.
21. The example given in para 91 on the amount of additives proposed for use in butter (110 additives in the draft GSFA, 8 in the butter standard) supports what is said above.
22. As an editorial comment, the EC would like to recommend that when the document describes the role of countries as members of Codex Alimentarius Commission, the same term would be used as in the Procedure Manual which is "Member countries" (instead of "Member States"). Furthermore, the following references mentioned in para 98 and 100 should be updated: Codex GSFA (CODEX STAND 192-1995, **Rev.3-2001**) and Class names and the INS for food additives (**CAC/GK 36-1989, Rev. 6-2001**).

IFU (The International Federation of Fruit Juice Producers):

The International Federation of Fruit Juice Producers IFU is very pleased to have the opportunity to comment on the above mentioned document, as the present differences between the additives allowed in the GSFA and those technologically justified and therefore foreseen in the Draft Codex General Standard on Fruit Juices and Nectars are a major concern of the global fruit juice industry.

During the elaboration of the first draft of a revised Fruit Juice Standard high priority was given to the list of additives. It is a major objective of our industry to keep fruit juices as natural and healthy as possible as this is the most important marketing argument in the competition with soft drinks. There is no doubt that for the consumer, who is interested in a natural product, a long list of additives is damaging the impression of a natural product. Many of the additives foreseen in the GSFA for fruit juices could be used to deceive the consumer, e.g. colours to upgrade a juice of bad quality, thickening agents to give a better mouth feeling of a watery juice. Therefore the list of additives, which has been established by the global fruit juice industry, represented in our Federation, is very short. Only 15 additives for fruit juices and nectars are foreseen so far, whereas in the GSFA 97 additives are mentioned.

The main reason for this situation results from the decision to accept that the "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" (para 39, 43). This principle may be appropriate for broad food categories in the GSFA, but not for standardised products, which are identical with the food category or a food subcategory.
Our Federation is therefore very pleased, that the 34th CCFAC decided "to reconsider whether the reporting by a Member State of the use of an additive is prima facia evidence of the technological need for the use of an additive" (para 60).

The answer to this question in the case of standardised products is a clear “no”. Discussions with some Member State delegations showed, that

- food categories in national legislations are often very broad (e.g. all beverages) and contain therefore additives which make sense for some foods in the same category, but are in the best case not necessary for a fruit juice and in the worst case can even not be used in a fruit juice.
- some additives have perhaps been used at the beginning of the last century, but in the meantime they have been replaced by more effective additives or by new technologies, but they are still in the national legislation.

The opinion of our Federation is therefore to abolish this principle for standardised products and to base the allowance of the use of an additive strictly on the technological justification, which has to fulfil clear criteria.

It is correct that different countries may have different needs regarding additives (para 79, 62, 50, 40). However, all Member States have the possibility to propose additives needed in their country during the elaboration of a commodity standard. No proposals have been made so far during the two Sessions of the Intergovernmental ad hoc Codex Task Force on Fruit and Vegetable Juices for additives which are not included in the 15 additives foreseen by the Task Force. Why should the GSFA therefore contain 97 additives?

Our Federation is therefore fully or partly in favour of several recommendations of this document:

- para 82: we support new work in order to amend the Preamble of the GSFA

- para 83: we propose the following amendment:

  a) For example:
  1.1 Permitted Food Additives

  …… 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.

  Comment: We recommend to base strictly on technological need.

- para 84: we support the development of a companion document to the preamble of the GSFA

- para 83: we are not in favour of the term “widely permitted” for use in food. However, in case that this wording would remain, we support a restrictive definition of this term.

- para 90, c) in the case of fruit and vegetable juices and nectars there is equivalence between the commodity standard and the GSFA food category. It is absolutely necessary that in such a case the list of additives of the commodity standard is consistent with the allowed additives in the GSFA.

- para 91: we fully support the statement made by some delegations, and the situation in the case of fruit juices and nectars is absolutely comparable with those mentioned for butter.

- para 94: we agree that the additive provisions of commodity standards be included in the GSFA but not superseded by the GSFA (see also our comment to para 90, c).

- para 100: we support the beginning of new work regarding the Preamble of the GSFA including a new section on the Relationship between the GSFA and Codex commodity standards.

We support all measures which lead to clear rules giving the competence to decide on the additives in the standardised product to the commodity committees within the limits of the general provisions for the use of additives. Under this aspect we support especially the last bullet of para 100.

ISDC (International Soft Drinks Council):

- **Background**

ISDC appreciates the excellent background section of the document.

- **Criteria for establishing food additive provisions**

We note the paragraph 62 in that "in the interests of free trade there should be greater recognition of, and tolerance shown towards, the variability of technological need among different nations". ISDC fully supports this statement. It is critical that Codex standards, recommendations, and guidelines be adequate to assure that the needs of all Codex countries are met. Current discussions within CCFAC on technological justification and use levels of additives frequently do not take this into account to the disadvantage of the food industry in some countries, particularly those in developing countries. One notable example is the on-going debate on the use of specific preservatives in foods and beverages.

Recommendations

Para 83

a) ISDC does not support the proposed amendment of point 1.1 of the Preamble to include *"or that are widely permitted for use in the food."* It is unclear to us how "widely permitted" would be defined. Would it be based on size of the population or a number of countries that permit an additive. For example, if the use of a food additive is permitted in two countries, such as in India and China with a combined population of about 2.3 billion, would it be considered "widely permitted"? Or would it be considered "widely permitted" if three countries, such as Canada, Mexico and the U.S that are the members of the North America Free Trade Agreement, permit an additive with a combined population of about 423 million? Decisions should not be solely based on the number of countries where a food additive is permitted. Characteristics of countries vary considerably and it would not be appropriate to compare them one to one in this situation.

b) ISDC generally agrees with adding a new section 3.5 as proposed, although we note that there are some additives that have high enough ADIs to warrant a GMP use level. For example, the ADIs for Caramel Color Class III and IV are both 200 mg/kg bw/day. CCFAC should consider permitting a GMP level for such additives on a case-by-case basis. Therefore, we would suggest amending the proposed first bullet so that it would read:

- ***Additives assigned a numerical ADI by JECFA should be assigned numerical maximum use levels in the GSFA, unless the ADI of an additive is considered high enough to permit assigning a GMP use level.***

c) ISDC agrees that the maximum level should be viewed as an upper bound of safe use, yet not excluding legitimate applications. In discussions within CCFAC, the maximum level often has been misunderstood as the typical level of use. ISDC agrees that the GSFA must be viewed as providing internationally acceptable maximum levels of use of additives in food. However, we do not understand the legal difference between maximum permissible levels and maximum acceptable

levels. If amending all references to maximum permissible levels in the GSFA to maximum acceptable levels will enhance consensus within CCFAC, we would accept the proposed change.

d) ISDC agrees with the proposed amendment.

Para 84:

ISDC supports developing a companion document to the Preamble that describes the operating principles and processes used by CCFAC to elaborate the food additive provisions in the GSFA to enhance transparency.

Para 85:

ISDC strongly agrees that a clearer definition is required for "widely permitted." Please see the comments made in point a) above.

Paras 86 and 87:

ISDC agrees with the proposed procedures.

IFAC:

The International Food Additives Council (IFAC) composed of food additive producers whose products are in international trade, has NGO status in the Codex Alimentarius Food Standards Programme, is extremely interested in development of the General Standard on Food Additives and has participated in the Working Group on thus project since its inception.

Based on our over three decades of experience in the work of CCFAC we file the following comments on CX/FAC 03/6 the "*Proposed Draft Preamble to the Codex General Standard for Food Additives"*.

2. IFAC joins with those organizations who have expressed thanks to the drafting group under the direction of France and the United States of America, which is endeavoring, to elaborate revisions to the Preamble of the GSFA. Considerable success has been achieved and should serve as a stimulus to continue work and finalize the GSFA.

   IFAC agrees with the six basic Principles for the Development of the GSFA as set out in paragraph II B 3 (page 2) of CX/FAC 03/6.

2. Paragraph 48 of CX/FAC 03/6 refers to the 30th CCFAC, which calls for establishment by at least two Codex Member States that they permit the use of the additive up to the Maximum Level proposed in Tables 1 and 2. It is stated that such would establish that trade may occur in the food containing the additive.

   IFAC disagrees

   IFAC believes that any trade of a food containing the additive, no matter how limited, comes within the described scope of the GSFA. If the stated goal for the GSFA of achieving an overarching, complete general standard is to be achieved, the GSFA should be as inclusive as possible.

3. Paragraph 81 points out that CCFAC has agreed in principle that all food additives having been assigned a numerical ADI by JECFA should also be assigned a numerical maximum use level. IFAC agrees with such a general principle, provided however, that the

numerical limitation also reflects Good Manufacturing Practice. The maximum use of a food additive, therefore, should be one that accomplishes the intended technical use and no more.

IFAC also agrees and recommends that additives assigned a "Not Limited" or "Not Specified" ADI by JECFA should be assigned GMP maximum levels for their use in Tables 1 and 2 of the GSFA.

4. The proposed draft preamble now states in paragraph 82 that the Committee may wish to propose as new work the amendment of the Preamble with a view toward establishing maximum use level provisions in the GSFA.

   IFAC notes that the recently published survey results on the function of the Codex Alimentarius recommends that no new work be taken on in Codex unless safety related. As there already is in place a mechanism to publish the maximum use level provisions in the GSFA, IFAC proposes deletion of paragraph 82 in word and substance.

5. IFAC also reads with interest, the possible amendments to the Preamble by including the reference to "additives considered to be technologically necessary or which are < *widely permitted for use in food*> (emphasis added).

   IFAC joins with those who have asked what does "widely permitted" mean? "Widely permitted" geographically ? or in numerous foods? or used in large amounts? IFAC suggests deletion of such terminology as such criteria are at odds with sound scientifically supported inclusions in the GSFA. Even limited use of a food additive, geographically or in number of food products or in amounts added to food are all justifiable reasons for inclusion in the GSFA.

6. IFAC expresses its reservations over the language contained in paragraph 100.
   A new section 1.2 is listed which reads, in part;

   "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"

   IFAC believes such language runs counter to the general principles behind the GSFA. If adopted, such language would re-burden the CCFAC with the system, shown to be largely ineffective, of establishing restrictive positive lists as parts of vertical (commodity) standards. The WG on the GSFA, CCFAC and the Commodity Committees should take into account the agreed upon policy of moving away from vertical (recipe) standards in favor of horizontal more inclusive standards.

7. Paragraph 100 goes on to propose that the Food Additives and Contaminants Section in the Procedural Manual on the relationship between Codex Commodity Committees and the General Committees be replaced by the text contained in Annex II of CX/FAC 03/6.

   A reading of the subject Annex contains among other remarks;

   "Codex Commodity Committees should prepare a section on food additives in each draft commodity standard".

   "The Codex Commodity Standards should reference the GSFA" but adds "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". IFAC proposes deletion.

   The Annex then goes on to state the food additive may used in accordance with the GSFA but adds; "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". IFAC proposes deletion.

IFAC submits the wording cited in Annex II runs counter to the basic tenets of the GSFA, returns food additive control entirely to the commodity committees, re-establishes vertical standards and thus stifles innovation and does not enhance consumer protection.

IFAC fully endorses the remarks in Annex II on Good Manufacturing Practices.

IFAC believes that the GSFA as set out, accurately takes into account that additives are used in standardized and/or in non-standardized foods.

A primary value of the GSFA is that, on completion, it will be inclusive, providing regulators, the regulated industry, consumers and governments a comprehensive up to date synopsis reflective of all food additive uses.

IFAC believes that a return to a vertical standard approach with its limited list of acceptable food additives inaccurately suggests to interested parties that only the food additives listed in Codex standardized foods are in use.

IFAC submits that a complete, frequently updated list of food additives accurately reflecting world-wide applications of food additive use best serves consumer protection, provides a sound basis to food additive regulation and facilitates removal of barriers to international trade.

IFAC appreciates this opportunity to comment on the important issue of the GSFA and its timely development.