codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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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-sixth Session

Rotterdam, The Netherlands, 22 -26 March 2004

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

COMMENTS AT STEP 3

The following comments have been received from: Australia, European Community (E.S.F.), Norway, United States of America, Federation of Food Additives and Food Enzymes Industries (ELC), Institute of Food Technologists (IFT), International Federation of Fruit Juice Producers (IFU), International Soft Drinks Council (ISDC)

AUSTRALIA

Comment 1:

The Australian Delegation has reviewed the draft Discussion Paper on the Preamble to the General Standard on Food Additives prepared by the Swiss Delegation and submitted to the Codex Secretariat on 10 December.

Australia notes with great concern that the significant comments that we and others (New Zealand and USA) have raised as members of the Working Group about the direction and emphasis of the draft discussion paper nor our suggested revisions and possible options are reflected in this latest version. For the information of those not directly involved in the Working Group, these suggested revisions and possible options included:

1. That the interpretation by the Swiss Delegation of the Terms of Reference given to the Drafting Group by the CCFAC was wrong and in fact is contrary to direction of the development of the GSFA agreed by the CAC. CAC made the original decision to develop the GSFA as a general standard. This decision was made in full knowledge that the responsibility for food additive regulation would shift from the Commodity Committees to CCFAC, and CAC and CCEXEC ahave subsequently endorsed the directions taken by CCFAC on numerous occasions as the GSFA evolved to its present form. In doing so the member countries have clearly agreed to the direction that Codex Committees should take in interpretation of the policies elaborated in the Procedural Manual and the General Principles for the Use of Food Additives. It is not appropriate to ignore this and instead, as the paper in its present form suggests, interpret the Terms of Reference of the Working Group in a way that does not have the endorsement of the CCFAC and CAC.

2. It was always understood that retrospective changes to the Procedural Manual would be required in recognition of the evolutionary shift in responsibilities between CCFAC and the Commodity Committees as the GSFA was developed. The function of the present Discussion Paper should be to facilitate this process.

3. There is a common thread running through the Discussion Paper in its present form that food additive uses for food categories corresponding to Codex Commodity Standards should be frozen and only changed by Commodity Committees. This direction is clearly out of step with the policies elaborated by CCFAC and endorsed by CAC for GSFA. In addition, there is a clear indication that Codex has decided to reduce emphasis on recipe-based Commodity Committees in favour of horizontal standards such as the GSFA.

4. Australia agreed with the approach suggested by the US Delegation to the Working Group to revise the Preamble to the GSFA to reflect CX/FAC 03/6 and comments contained in CX/FAC 03/6; to revise sections of the Codex Procedural Manual to reflect the directions endorsed by the CAC on the GSFA, and in particular clarify the relationship between Codex Commodity Committees and CCFAC by introducing a distinction between the roles of Commodity Commitees to comment on technological need and use for additives with that of CCFAC to decide on technological justification of an additive (combination of information obtained from Commodity Committees and information on safety and exposure obtained from all sources including JECFA). We also agreed to the suggestion by US to replace the Codex General Principles for the Use of Food Additives with the relevant section of the Preamble to the GSFA.

5. In the interest of moving the Codex process forward in a constructive manner, the US sunsequently submitted revised versions of the Preamble to the GSFA and the Codex Procedural Manual which Australia agreed with. It is significant that none of these comments, or the revisions of the Preamble to the GSFA or the Codex Procedural Manual submitted by the US Delegation, are referred to or contained in the draft Discussion Paper.

Australia therefore formally requests an explanation from the Drafting Group Leader as to why the significant concerns raised by Australia and half of the Working Group on several occasions were not included in the Discussion Paper. At present the only reference to these significant concerns is a misleading reference included in the paper under paragraph 5: "There was a clear division among the members of the Working Group as to the interpretation of its mandate as one group of members (Australia, USA and New Zealand) clearly understood this mandate to mean the contrary of what the second group (Denmark, france, Switzerland, the EC, CEFS and IFU) believed it to be. The Draft Discussion Paper was amended in light of the submitted comments".

The content of this paragraph is inadequate and misleading and is not a true reflection of the seriousness of the division between the various members of the Working Group. As an example of this division, Australia, together with New Zealand and USA, called for the abandonment of the Discussion Paper on several occasions and did not comment at all on sections 2 and 3 of the paper. And yet the paper has been submitted in its present form with the implication that all members of the Working Group had full input into its content. None of this history is reflected in the draft Discussion Paper. Indeed, there is no indication of any of the individual Working Group member's comments in the paper, as would be expected under the normal procedure to document these comments to make the process open and transparent for all CCFAC members. Instead, the concerns, comments and efforts made by several of the Working Group members have been ignored.

Therefore, Australia formally requests the following of Codex and CCFAC :

1. That the Working Group Leader provide an explanation as to why neither the significant concerns that we and others have raised to the drafting group about the direction and emphasis of the draft discussion paper nor our suggested revisions and possible options are reflected in this latest version of the Discussion Paper.

2. That the Codex Secretariat circulate this formal letter from the Australian Delegation to all CCFAC member countries as Australia's response to the Discussion Paper on the Preamble to the General Standard on Food Additives so that all CCFAC member countries are fully aware of the divisions within the Working Group and the issues raised.

3. Given the clear disagreement amongst the Working Group members, that the paper **not** be tabled at the next CCFAC in its present form.

Comment 2:

We have previously noted our strong concerns regarding the scope and emphasis of this draft paper as follows:

1. Australia continues to believe that the paper is unacceptable as written and needs substantial changes to the scope and focus to ensure consistency with the agreed directions taken by the CCFAC and the CAC on the development of the GSFA. This solution is also suggested by the FAO Joint Secretary to JECFA in relation to the issue of consistency of Codex Commodity Standards and the GSFA and the fundamental disagreements about how food additives shall be regulated (e.g. methods to be used for determination of use levels)

2. However, Australia is very concerned about the issue raised by the Swiss Chair's conduct in progressing the paper, and indeed the conduct of Codex drafting groups and whether consensus or "majority rule" will be the norm in advancing the Codex process. Although finding consensus is not an easy task when drafting Codex documents, Australia believes that the chairs of drafting groups should strive to find common ground to advance the Codex process. It is Australia's understanding that consensus is still the mainstay of the Codex decision-making process and this was obviously not the case in this particular instance.

3. Australia believes that the implication that the majority rules, as opposed to consensus, is not a valid justification for a Codex document that is so obviously controversial as judged by half of the Working Group members and that this is setting an unwelcome precedent in the Codex process.

4. Australia has previously shown its support for the Codex Commission's affirmation on emphasis on elaboration of horizontal standards, particularly in relation to the elaboration of the GSFA. Australia therefore notes with concern the direction that the discussion paper takes which is counter to the horizontal standard-setting emphasis of the Codex Commission. We reiterate that the emphasis, conclusions and recommendations of this paper are inconsistent with CAC decisions and may lead to CCFAC and other Codex Committees reverting to a vertical standards-setting approach and away from general subject standards. Any decision to change the emphasis back to vertical standard-setting should be made by the CAC in an open and transparent manner, and not by the Chair or leader of a drafting or working group.

5. Therefore, Australia supports the approach taken by the US Delegation, also supported by New Zealand, that the most constructive way forward is to rewrite the General Principles and the Procedural Manual as a matter of priority to make them consistent with the endorsed (by CCFAC and CAC) approach to the development of the GSFA. We again express our regret that CX/FAC 04/36/6 was finally distributed by the Swiss Chair without taking into account the very useful contributions made by 50% of the working group members, including efforts to rewrite the General Principles and the Procedural Manual. Whereas Australia recognises the time constraints when leading a working group, three members of the working group were not even given the courtesy of reading the final version of the discussion paper.

6. For the 36th CCFAC, Australia urges all members to remember that the GSFA is not completed and that we need to focus on those issues which require changes (Preamble, Procedural Manual) and on the food additives still waiting to be included in the GSFA. There are limited resources that have to be allocated in the best and most efficient manner. In relation to this last point, some of the recommendations made in the discussion paper have major implications for a re-working of the whole of the GSFA.

7. Australia's aim is to work to reach consensus on how to address the issues of the relationship between the GSFA and commodity standards that is consistent with the Commission's mandate to focus on the elaboration of horizontal standards while revising the vertical commodity standards by minimising their provisions to essential quality factors. It is worthy of note that the recent evaluation of the work of Codex also agreed that the focus of Codex should be on a horizontal standard setting approach as opposed to vertical standards. Australia looks forward to working with CCFAC members to reach consensus on a way forward on some of the contentious issues and make progress by developing feasible proposals.

EUROPEAN COMMUNITY (English version):

The European Community thanks the Chair of the Working Group for the considerable time and effort put into this draft discussion paper on the Preamble of the GSFA. The European Community thinks that this document provides a very good basis for discussion and for the review of the Preamble of the GSFA.

The European Community would like to recall that the 35th session of the CCFAC agreed to review the Preamble to the GSFA in order to comply with the General Principles for the Use of Food Additives and the Codex Alimentarius Commission Procedural Manual (see paragraphs 47 & 48, Alinorm 03/12A). With this it endorsed Recommendation 3 of the report of the ad hoc working group on the GSFA (see CRD 1), stating that the Preamble should be reviewed in order to ensure compliance with the General Principles for Food Additives and the Procedural Manual.

Please find below more specific comments to the different sections of the Working Paper.

Section 1: Review of the preamble to the GSFA

This section outlines how the preamble of the GSFA has developed since the first draft was published in 1992 and analyses in how far the preamble complies with the General Principles and the Procedural Manual. At the end of the section, three recommendations for the review of the preamble are given:

***Recommendation* 1**

This recommendation foresees that the Codex Alimentarius Commission clarifies the relationship between the GSFA and the Commodities Committees to resolve the inconsistencies between these two sets of Standards.

The European Community cannot agree with this recommendation, since the Procedural Manual already defines the relationship between the GSFA and the Commodity Committees. According to the terms of reference of the Working Group the Preamble should be revised in this point to comply with the Procedural Manual.

As stated in the Procedural Manual, where an active Commodity Committee exists, proposals for the use of additives on any commodity standard under consideration should be prepared by the Committee concerned, and forwarded to the Codex CCFAC for endorsement. Where no active Commodity Committee exists, proposals for new additive provisions or amendments of existing provisions should be forwarded directly by member countries to the CCFAC.

It should be kept in mind that this approach ensures that different technological needs for food additives of all Codex Member States are acknowledged, since the Codex Commodity Standards are world-wide Standards developed with the input of all Codex Member States. It is precisely the Commodity Committees that have the best knowledge about the technological need and types of additives used in foods regulated by a commodity standard.

Furthermore the European Community is of the view that the Commodity Standard should not only list permitted technological functions, but also the specific additives that achieve this technological function. The European Community agrees that to list only the technological function would simplify the Commodity Standard, but not all the additives within the same functional class have the same efficacy in food. Therefore, also as guidance to food manufacturers, specific food additives should be listed in addition to the functional classes permitted in a commodity. Moreover, if no numerical maximum levels are set for additives with an numerical ADI, it is difficult to control the intake of these additives.

Recommendation 2

The European Community supports that point 6 of the General Principles which states that the inclusion of food additive 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 ADI established for the food additive is included in section 1.2 of the Preamble, as proposed in this recommendation.

In the European Community's view, these principles can be applied to both additives for which a numerical ADI has been established and additives with an ADI not specified. When applied to additives with a numerical ADI, the application of these principles would ensure these additives are only authorised in specific foods and with numerical maximum levels, as concluded by the 34th session of the CCFAC and endorsed by the 35th session (see Alinorm 03/12A paragraph 44). For additives with an ADI not specified, which are allowed in foodstuffs in general according to Table 3 of the GSFA, these principles should be understood as guidance to the food manufacturer using the additive.

Recommendation 3

This recommendation takes up a decision taken by the CCFAC in 1999, stating that the GSFA should take into account the endorsed food additives provisions contained in the Commodity Standards. The European Community can agree with this recommendation.

Section 2

This section outlines the procedures used in the development of the GSFA and its current format. Three recommendations (1, 2 and 3) are given to improve the structure and format of the GSFA. The European Community agrees with these recommendations.

The European Community also agrees with the recommendation given in paragraph 91 of this section, which foresees that definitions of all relevant terms used in the GSFA should be included in the preamble. The European Community is of the view that definitions are of fundamental importance to the understanding of the GSFA. Therefore, the European Community agrees with the recommendation that the relevant definitions should be contained in the preamble of the GSFA.

Point 2.3 of this section gives a step by step approach to the use of the GSFA. To illustrate this approach, two examples are given. The European Community is of the view that such guidance facilitates the use of the GSFA and that it would be useful to take up this information in an accompanying document to the GSFA.

Section 3

This section reviews the policy for selecting maximum levels of use for inclusion in the GSFA.

Paragraph 103 under this section stresses that the technological needs for food additives differ from country to country, partly due to availability of raw materials, the climate, the advancement of the food technology used in production etc. The European Community fully acknowledges this and would like to ensure that the policy for selecting maximum levels of use ensures that the different technological needs of Codex member countries are taken into account.

For standardised commodities, as outlined above, it is precisely the Commodity Committees that have the necessary technological expertise to define the technological need for the use of food additives in the commodities concerned. Therefore, the European Community supports recommendation 1 of this section, that for standardised commodities, the GSFA should only list the additives contained in the Commodity Standards.

It should be kept in mind that according to the Procedural Manual, the additive provisions in the Commodity Standard need to be endorsed by the CCFAC. In case of disagreement the provisions in question can either be sent back to the Commodity Committee concerned or amended by the CCFAC.

For non standardised commodities, the Procedural Manual lays down that food additive usage and maximum levels are based on the proposals by the Member Countries of Codex. The recommendation foresees that the following text is included in the preamble for the case that two or more Member Countries propose different maximum levels:

i) the lowest reported level of use is taken as the starting point for discussion

ii) If a Codex Member Country considers that a proposed level of use is too low, the Member Country 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 the 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.

In the European Community's view, this procedure ensures that the different technological needs for food additives are taken into account, while fully respecting point 6 of the General Principles (see section 1, recommendation 2). Therefore, the European Community can fully support the inclusion of this text in the preamble.

In summary, the European Community can agree with the content of the discussion paper, with the exception of recommendation 1 in Section 1.

EUROPEAN COMMUNITY (Spanish version):

La Comunidad Europea agradece a la Presidencia del Grupo de Trabajo todo el tiempo y el esfuerzo que han dedicado a este documento de debate sobre el Preámbulo de la NGAA, y considera que este documento ofrece una base muy buena para discutir y revisar dicho Preámbulo.

La Comunidad Europea desearía recordar que en la 35ª reunión del Comité del Codex sobre Aditivos Alimentarios y Contaminantes de los Alimentos (CCFAC) se acordó revisar el Preámbulo de la NGAA a fin de cumplir lo establecido en los Principios Generales para el Uso de Aditivos Alimentarios y el Manual de Procedimiento de la Comisión del Codex Alimentarius (véanse los apartados 47 y 48 de Alinorm 03/12A). Con ello se refrendaba la recomendación nº 3 del informe del grupo *ad hoc* dedicado a la NGAA (véase CRD 1), según la cual debía revisarse el Preámbulo para garantizar el cumplimiento de los Principios Generales para el Uso de Aditivos Alimentarios y del Manual de Procedimiento.

A continuación se exponen observaciones más específicas sobre las distintas secciones del documento de trabajo.

Sección 1: Revisión del Preámbulo de la NGAA

En esta sección se esboza la manera en que ha ido desarrollándose el Preámbulo de la NGAA desde que se publicara el primer proyecto en 1992, y se analiza el grado en que se ajusta a los Principios Generales y al Manual de Procedimiento. Al final de esta sección se hacen tres recomendaciones para su revisión:

Recomendación nº 1

En ella se prevé que la Comisión del Codex Alimentarius esclarezca la relación entre la NGAA y las normas elaboradas por los comités del Codex para productos, a fin de resolver las incoherencias entre ambos conjuntos de normas.

La Comunidad Europea no puede sumarse a esta recomendación, pues el Manual de Procedimiento define ya la relación existente entre la NGAA y las normas de los comités para productos. De acuerdo con el mandato del Grupo de Trabajo, habría que revisar el Preámbulo a este respecto para conformarlo al Manual de Procedimiento.

Tal como establece el citado Manual de Procedimiento, cuando hay en activo un comité para productos, las propuestas para utilizar aditivos alimentarios en cualquier norma sobre productos que se esté examinando han de ser preparadas por el comité correspondiente y remitidas al CCFAC del Codex para su aprobación. De no existir ningún comité en activo, los países miembros deben enviar directamente al CCFAC las propuestas para añadir nuevas disposiciones o modificar las disposiciones existentes relativas a aditivos.

Debe tenerse presente que este planteamiento da cabida a las diferentes necesidades tecnológicas, relacionadas con los aditivos alimentarios, de todos los países miembros del Codex, puesto que las normas del Codex sobre productos son normas de carácter mundial con aportaciones de todos los países miembros. Son precisamente los comités para productos los que mejor conocen las necesidades tecnológicas y los tipos de aditivos utilizados en los alimentos regulados por una norma sobre productos.

Además, la Comunidad Europea opina que una norma sobre productos no debe únicamente enumerar las funciones tecnológicas permitidas, sino también los aditivos concretos que se ajustan a esa función tecnológica. Está de acuerdo en que, si sólo se enumeraran las funciones tecnológicas, se conseguiría simplificar la norma correspondiente, pero no todos los aditivos de la misma clase funcional tienen la misma eficacia en los alimentos. Así pues, además de las clases funcionales permitidas en un producto deberían enumerarse también los aditivos alimentarios específicos, lo que, además, serviría de orientación a los fabricantes de alimentos. Por otro lado, si no se establecen dosis máximas numéricas para los aditivos con una IDA numérica, es difícil llevar un control de la ingesta de estos aditivos.

Recomendación nº 2

La Comunidad Europea está de acuerdo en que el párrafo 6 de los Principios Generales, según el cual la inclusión de un aditivo alimentario en una norma alimentaria deberá:

a) en la medida de lo posible, limitarse a alimentos específicos para usos específicos y en condiciones específicas;

b) estar en la dosis mínima de uso necesaria para conseguir el efecto deseado y,

c) en la medida de lo posible, tener en cuenta toda IDA establecida para el aditivo alimentario en cuestión, se incluya en la sección 1.2 del Preámbulo, tal como propone esta recomendación.

En opinión de la Comunidad Europea, estos principios pueden aplicarse tanto a los aditivos para los que se ha establecido una IDA numérica, como a los aditivos con una IDA no específica. En el primer caso, la aplicación de estos principios garantizaría que tales aditivos sólo se autorizaran en determinados alimentos y con unas dosis máximas numéricas, que es la conclusión a la que se llegó en la 34ª reunión del CCFAC y que fue refrendada en la 35ª reunión (véase el apartado 44 de Alinorm 03/12A). En cuanto a los aditivos con una IDA no específica, que están autorizados en los productos alimenticios en general conforme al cuadro 3 de la NGAA, estos principios deben entenderse como una guía para el fabricante de alimentos que utiliza dichos aditivos.

Recomendación nº 3

Esta recomendación incorpora una decisión tomada por el CCFAC en 1999, según la cual la NGAA debe tener en cuenta las disposiciones relativas a aditivos alimentarios contenidas en las normas del Codex para productos. La Comunidad Europea está de acuerdo con esta recomendación.

Sección 2

En esta sección se esbozan los procedimientos empleados para la elaboración de la NGAA y su actual formato, y se hacen tres recomendaciones (numeradas del 1 al 3) para mejorar su estructura y formato. La Comunidad Europea está de acuerdo con las tres recomendaciones.

También lo está con la recomendación hecha en el apartado 91 de esta sección, que prevé que se incluyan en el Preámbulo las definiciones de todos los términos relevantes utilizados en la NGAA. La Comunidad Europea cree que las definiciones revisten una importancia fundamental para comprender la NGAA y, por lo tanto, está de acuerdo con la recomendación de incluirlas en su Preámbulo.

El punto 2.3 de esta sección expone un enfoque gradual del uso de la NGAA y ofrece dos ejemplos para ilustrarlo. La Comunidad Europea opina que esta guía facilita el uso de la NGAA y que sería útil incorporar esta

En esta sección se pasa revista a la política para seleccionar las dosis máximas de uso para su inclusión en la NGAA.

En el apartado 103 se hace hincapié en que las necesidades tecnológicas para el uso de aditivos alimentarios difieren de un país a otro, en parte debido a la disponibilidad de materias primas, al clima, al grado de desarrollo de la tecnología alimentaria empleada en la producción, etc. La Comunidad Europea comparte plenamente esta idea y quisiera asegurarse de que la política para seleccionar las dosis máximas de uso garantiza que se tengan en cuenta las diferentes necesidades tecnológicas de los países miembros del Codex.

Por lo que se refiere a los productos normalizados, como se ha dicho anteriormente, son precisamente los comités para productos los que cuentan con la experiencia tecnológica necesaria para definir las necesidades tecnológicas relacionadas con el uso de aditivos alimentarios en los productos afectados. Así pues, la Comunidad Europea está de acuerdo con la recomendación nº 1 de esta sección, según la cual la NGAA sólo debe enumerar, para los productos normalizados, los aditivos incluidos en las normas sobre productos.

Debe tenerse presente que, de acuerdo con el Manual de Procedimiento, las disposiciones sobre aditivos contenidas en una norma sobre productos deben ser aprobadas por el CCFAC. En caso de discrepancia, tales disposiciones pueden o bien ser devueltas al comité para productos afectado, o bien ser modificadas por el CCFAC.

Tratándose de productos no normalizados, el Manual de Procedimiento establece que el uso de los aditivos alimentarios y sus dosis máximas se base en las propuestas de los países miembros del Codex. La recomendación nº 2 prevé que se incluya en el Preámbulo el siguiente texto, para el caso en que dos países miembros propongan dosis máximas divergentes:

«i) como punto de partida para las deliberaciones se toma la dosis más baja comunicada;

ii) si un Miembro del Codex considera que la dosis máxima de uso propuesta para un aditivo alimentario es demasiado baja, tendrá que proporcionar datos que demuestren que la DM de uso propuesta es tecnológicamente insuficiente y que una dosis más elevada no supondría ningún riesgo para la salud de los consumidores ni defraudaría al consumidor sobre la naturaleza del alimento. Debe procurarse que los debates sobre el riesgo para la salud pública, la necesidad tecnológica o la defraudación de los consumidores se basen en alimentos o clases de alimentos idénticos o equivalentes.»

En opinión de la Comunidad Europea, este procedimiento garantiza que se tengan en cuenta las diferentes necesidades tecnológicas para el uso de aditivos alimentarios, al tiempo que se respeta plenamente lo establecido en el párrafo 6 de los Principios Generales (véase la recomendación nº 2 de la sección 1). Por lo tanto, la Comunidad Europea está totalmente de acuerdo con que se incluya este texto en el Preámbulo.

En resumen, la Comunidad Europea está de acuerdo con el contenido del documento de debate, a excepción de la recomendación nº 1 de la sección 1.

EUROPEAN COMMUNITY (French version)

La Communauté européenne remercie le président du groupe de travail pour le temps et l'énergie investis sans compter pour rédiger l'avant-projet de révision du préambule de la NGAA. Elle considère que ce document fournit une bonne base de discussion pour le réexamen dudit préambule.

La Communauté européenne souhaite rappeler qu'il a été décidé, lors de la 35ème session du CCFAC, de revoir le préambule de la NGAA afin de respecter les principes généraux régissant l'utilisation des additifs alimentaires et le manuel de procédure de la Commission du Codex Alimentarius (voir paragraphes 47 et 48, Alinorm 03/12A). La session a donc approuvé la recommandation 3 du rapport du groupe de travail ad hoc sur la NGAA (voir CRD 1) selon lequel le préambule devait être réexaminé en vue de garantir sa conformité aux principes généraux régissant l'utilisation des additifs alimentaires et au manuel de procédure.

Des observations plus spécifiques sur les différentes sections du document de travail sont présentées ci-après:

Section 1: Réexamen du préambule à la NGAA

Cette section présente l'évolution du préambule à la NGAA depuis la publication de la première version en 1992 et analyse sa conformité aux principes généraux et au manuel de procédure. À la fin de cette section, trois recommandations sont formulées pour le réexamen du préambule:

Recommandation 1

Cette recommandation prévoit que la Commission du Codex Alimentarius clarifie la relation entre la NGAA et les normes de produits afin de supprimer les incohérences existant entre ces deux normes.

La Communauté européenne ne peut approuver cette recommandation étant donné que le manuel de procédure définit déjà la relation entre la NGAA et les comités des produits. Conformément au mandat du groupe de travail, ce point du préambule doit être réexaminé afin de respecter le manuel de procédure.

Selon le manuel de procédure, lorsqu'il existe un comité de produits, les propositions pour l'emploi d'additifs dans toute norme alimentaire qui est à l'étude, doivent être préparées par le comité concerné et transmises au CCFAC pour approbation. En l'absence de comité de produit, les propositions de nouveaux additifs ou de modification des dispositions existantes doivent être envoyées directement par les États membres au CCFAC.

Il convient de garder présent à l'esprit que cette approche garantit la prise en compte des différents besoins technologiques de tous les États membres en matière d'additifs alimentaires, étant donné que les normes de produits Codex sont des normes internationales élaborées grâce aux contributions de tous les États membres du Codex. Ce sont précisément les comités de produits qui sont les mieux informés des besoins technologiques et des types d'additifs utilisés dans les produits alimentaires régis par une norme de produit.

En outre, la Communauté européenne est d'avis que la norme de produit ne doit pas seulement énumérer les fonctions technologiques mais également les additifs spécifiques assurant cette fonction technologique. La Communauté européenne approuve l'idée selon laquelle l'énumération des fonctions technologiques seules simplifierait la norme de produit mais il se trouve que les additifs d'une même classe fonctionnelle n'ont pas tous la même efficacité dans les aliments. Par conséquent, à titre d'orientation pour les fabricants, il conviendrait d'énumérer les additifs alimentaires spécifiques en plus des classes fonctionnelles autorisées pour un produit. En outre, si aucune teneur maximale n'est fixée pour les additifs ayant une DJA spécifiée, il est difficile de contrôler la dose journalière pour ces additifs.

Recommandation 2

La Communauté européenne est d'avis que le point 6 des principes généraux, selon lequel un additif alimentaire devrait être inclus dans une norme de produit:

d) en se limitant autant que possible à des aliments spécifiques pour des buts spécifiques et dans des conditions spécifiques,

e) à un niveau aussi faible que possible pour obtenir l'effet recherché,

f) en tenant compte autant que possible de toute DJA préétablie, doit être inclus dans la section 1.2 du préambule, comme proposé dans cette recommandation.

La Communauté européenne considère que ces principes peuvent être appliqués à la fois aux additifs ayant une DJA spécifiée et aux additifs sans DJA spécifiée. Appliqués à des additifs ayant une DJA chiffrée, ces principes garantiront une utilisation des additifs limitée à certains aliments et respectant des teneurs maximales, conformément aux conclusions de la 34ème session du CCFAC qui ont été approuvées lors de la 35ème session (voir Alinorm 03/12A, paragraphe 44). Pour les additifs sans DJA autorisés dans les aliments en général conformément au tableau 3 de la NGAA, ces principes font office d'orientations pour le fabricant de produits alimentaires utilisant l'additif en question.

Recommandation 3

Cette recommandation reprend une décision prise par le CCFAC en 1999 selon laquelle la NGAA devrait tenir compte des dispositions relatives aux additifs alimentaires approuvées et intégrées dans les normes de produits. La Communauté européenne peut approuver cette recommandation.

Section 2

Cette section définit les procédures utilisées dans l'élaboration de la NGAA et le plan de présentation actuel de celle-ci. Trois recommandations (1, 2 et 3) ont été formulées afin d'améliorer la structure et le plan de présentation de la NGAA. La Communauté européenne se rallie à ces recommandations.

La Communauté européenne approuve également la recommandation formulée au paragraphe 91 de cette section, qui prévoit d'intégrer dans le préambule la définition de tous les termes importants employés dans la NGAA. La Communauté européenne est d'avis que ces définitions sont fondamentales pour la compréhension de la NGAA. Aussi la Communauté européenne se rallie-t-elle à la recommandation qui prévoit de placer les définitions dans le préambule de la NGAA.

Le point 2.3 de cette partie présente la procédure par étapes de l'utilisation de la NGAA. Cette procédure est illustrée à l'aide de deux exemples. La Communauté européenne considère que ces indications facilitent l'utilisation de la NGAA et qu'il serait utile de les reprendre dans un document accompagnant la NGAA.

Section 3

Cette section examine la politique de sélection des limites d'utilisation maximales à inclure dans la NGAA.

Le paragraphe 103 de cette section souligne que les besoins techniques en additifs alimentaires varient d'un pays à l'autre, en partie en raison de la disponibilité des matières premières, du climat, de l'avancement de la technologie alimentaire utilisée dans la production etc. La Communauté européenne souscrit entièrement à cette remarque et voudrait être certaine que la politique de sélection des limites d'utilisation maximales prendra en considération les différents besoins technologiques des pays membres du Codex.

Ainsi qu'il a été indiqué précédemment, dans le cas des produits normalisés, ce sont les comités de produit qui possèdent les connaissances spécialisées nécessaires pour définir les besoins technologiques liés à l'utilisation des additifs alimentaires dans les produits concernés. Par conséquent, la Communauté européenne souscrit à la recommandation n° 1 de cette section, selon laquelle, pour les produits normalisés, la NGAA devrait dresser uniquement la liste des additifs alimentaires contenus dans les normes du Codex.

Il convient également de noter que, selon le manuel de procédure, les dispositions en matière d'additifs alimentaires doivent être confirmées par le comité du Codex sur les additifs alimentaires et les contaminants (CCFAC). En cas de désaccord, les dispositions en question peuvent soit être renvoyées au comité des produits, soit être modifiées par le CCFAC.

Pour ce qui est des produits non normalisés, le manuel de procédure dispose que l'usage des additifs alimentaires et les limites maximales reposent sur les recommandations des pays membres du Codex. La recommandation prévoit d'inclure le texte suivant dans le préambule lorsque plusieurs pays membres proposent des limites maximales différentes:

i) la concentration la plus basse rapportée sert de point départ à la discussion;

ii) si un membre du Codex considère que la limite d'utilisation maximale proposée pour un additif alimentaire est trop faible, ce membre du Codex doit alors fournir les données prouvant que la LM d'utilisation est technologiquement insuffisante et qu'une LM d'utilisation plus élevée ne présente pas de danger pour la santé des consommateurs et ne va pas l'induire en erreur sur la nature de l'aliment. Il faudrait s'assurer que les données portent sur des aliments identiques ou équivalents.

De l'avis de la Communauté européenne, cette procédure assure la prise en considération des différents besoins technologiques liés aux additifs alimentaires et le parfait respect du point 6 des principes généraux (voir section 1, recommandation n° 2). Par conséquent, la Communauté européenne est tout à fait favorable à l'inclusion de ce texte dans le préambule.

En résumé, la Communauté européenne fait sien le contenu du document de réflexion, à l'exception de la recommandation n° 1 de la section 1.

NORWAY:

Norway would like to thank the Working Group for their work on the proposed draft preamble of the Codex General standard for Food Additives (GSFA) and would like to make some comments. Like the Working Group, Norway supports the development of a horizontal standard for food additives in order to achieve the Codex objective of protecting consumers and ensuring fair trade practices.

Section 1 Review of the preamble to the GSFA

Recommendation 2 proposes that article 6 of the General Principles for the Use of Food Additives is included in the preamble of the GSFA. According to these principles 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 assessment established for the food additive and the probable daily intake from all sources.

Norway agrees with the majority of the Working Group that the development of the GSFA is not in compliance with the principles given in article 6 of the Gener+al Principles, and thus supports recommendation 2 that these principles are included in the preamble, given that "specific foods" in article 6(a) means food categories as used in the Food Category System of the GSFA.

Recommendation 3 proposes that the CCFAC takes note of the recommendation made to it by the Codex Alimentarius Commission in 1999, which states: "prior to its publication, the General Standard should take into account the endorsed food additives provision contained in Codex Commodity standards". Norway agrees to recommendation 3.Section 2 Accompanying Document for the Codex GSFA

Norway agrees to the recommendations 1, 2 and 3 of Section 2.1. The recommendation concerning the Technical Procedures used in the development of the GSFA will in our opinion contribute to a clarification of the structure of the GSFA.

The majority of the Working Group recommends in 2.2 Definitions and Terminology Used in the GSFA, that the term "widely used" be defined in the preamble of the GSFA in order to achieve a common understanding of it within the Codex. Norway supports this recommendation as the term has been questioned on several occasions. Furthermore we agree to that the definition should be included the Preamble.

Norway also agrees to the recommendation that the step-by-step approach proposed in section 2.3 should be used to determine which food additives are recommended by the GSFA in a food commodity. It could be useful to take up this information in an accompanying document to the GSFA.

Section 3 Review of the Policy for Selecting Maximum Levels for Use for Inclusion in the GSFA.

The use of and technological need for food additives depends on several factors. Important factors in this regard are climate, availability of raw materials and the advancement of the food technology used in production.

Norway agrees that both the CCFAC and the Codex Commodity Committees have expertise in the field of food additives. Norway agrees to recommendation 1 that for standardised foods only those food additives that are recommended for use by Commodity Standards should be listed. But Norway would like to add that Commodity Standards should not only list permitted technological functions, but also the specific food additives that achieve this technological function in order to provide guidance to the manufacturers, and to facilitate the monitoring of the use of food additives. In addition, for food additives with a group ADI (such as sorbic acid and sorbates) the limit for the food additive(s) should in general be given for the group and not single substances within this group.

Norway agrees to recommendation 2. The inclusion of this text in the preamble will result in a procedure that ensures that the different technological need for food additives will be taken into account.

UNITED STATES OF AMERICA:

The Working Group was charged by the 35th CCFAC (ALINORM 03/12A, para. 47):

- To review the Preamble to the GSFA in order to comply with the General Principles for the Use of Food Additives (Section 5.1, Volume 1A of the Codex Alimentarius) and the Codex Alimentarius Commission Procedural Manual, including Relations Between Commodity Committees and General Committees (pages 94 – 100, 13th ed), and the consideration of maximum levels of use for food additives proposed by Commodity Committees;
- To develop an accompanying document for the GSFA to describe the technical procedures used by CCFAC in the development of the GSFA, plus definitions and terminology and a step-by-step approach in the use of the GSFA, and;
- To review the policy for selecting maximum levels of use for inclusion in the GSFA as a matter of the highest priority.

The Committee also agreed (ALINORM 03/12A, para. 48) that the review of the Preamble, with a view to its revision, should take into account document CX/FAC 03/6 (Proposed Draft Revised Preamble to the Codex General Standard for Food Additives), specifically as related to paragraph 100 (Recommendations), as well as the discussions held at the 35th session on this subject and comments submitted (CX/FAC 03/6-Add. 1 and CRD 5).

Before addressing the specific recommendations of the discussion paper, the United States expresses its concern that this paper has not met its charge to clarify the relationship between the GSFA and Codex commodity standards. Rather, by its failure to recognize that the GSFA is an evolving standard and by its numerous inaccuracies and misrepresentations, this paper contributes to further misunderstandings within Codex.

To give one example of the inaccuracies in the discussion paper, we call attention to the information contained in Table No.1. The Table notes that 96 additives in the GSFA are listed for use in food categories 14.1.2-14.1.3.4. In fact, only 3 additives have been adopted at Step 8 for use in these food categories. The other 93 additives are at intermediate steps in the eight-step Codex process for standards elaboration. Similarly, the Table states that 111 additives in the GSFA are listed for butter. In fact, only 2 additives in the GSFA have been adopted at Step 8 by the Commission.

Moreover, the discussion paper completely ignores its mandate from the 35th CCFAC to take into account paragraph 100 of CX/FAC 03/6, as well as CX/FAC 03/6 Add.1 and CRD 5 (35th CCFAC). These documents all contain substantive recommendations for revising the Procedural Manual and the GSFA Preamble in order to clarify the relationship between the food additive provisions in the GSFA and Codex commodity standards and to advance the horizontal standard-setting process in Codex.

The discussion paper implies that the CCFAC inadvertently created the existing inconsistencies among the GSFA, the Procedural Manual, and commodity standards. We believe this to be an inaccurate interpretation of the record, as ample documentation exists to show that the CCFAC has acted in direct response to decisions by the CAC; and the CAC has, on numerous occasions, endorsed the direction taken by the CCFAC as the GSFA has evolved to its present form. Furthermore, the CAC endorsed the development of the GSFA with the full expectation that temporary inconsistencies with commodity standards would arise. In doing so, the CAC emphasized that such inconsistencies should not delay development of the GSFA and other general subject standards.

The United States provided substantial comments to the drafting group that highlighted our concerns on the first draft of the discussion paper. However, we did not have the opportunity for further comment before the document was finalized. As such, the final statement in paragraph 2 of CX 04/36/6 is incorrect. The United States did not declare its disagreement with the final conclusions and recommendations because it had not seen them.

COMMENTS ON RECOMMENDATIONS OF THE DISCUSSION PAPER

Section 1: Review of the Preamble to the General Standard for Food Additives

Recommendation no. 1 (Paragraph 42): that "The CCFAC should request the Codex Alimentarius Commission to clarify the relationship between the CCFAC and the Commodity Committees with regard to food additive allocation for standardised foods."

The recommendation fails to take into account paragraphs 89-100 of CX/FAC 03/6, which discuss in detail the role of commodity standards and the elaboration of food additive provisions in the context of the GSFA. Paragraphs 89-100 of CX/FAC 03/6 include recommendations for amending the Preamble of the GSFA and the Procedural Manual to clarify the relationship between the GSFA and Codex commodity standards. The current discussion paper offers no proposal for a way forward for the Committee to consider.

In an effort to make progress, rather than requesting the CAC to clarify the relationship between the CCFAC and commodity committees, we propose that the CCFAC consider revisions to relevant sections of the Procedural Manual as contained in Annex 1 (attached) and to a revised Preamble as contained in Annex 2 (attached). These annexes build on the recommendations in paragraph 100 of CX/FAC 03/6 and the comments in CX/FAC 03/6-Add.1 and CRD 5 (35th CCFAC). We elaborate further on these annexes below.

Recommendation no. 2 (Paragraph 43): that "Paragraph 6 of the General Principles for the Use of Food Additives be included in Section 1.2 of the GSFA Preamble."

We submit that "Paragraph 6" is compatible with sections 1.2, 1.3, and 3.1 of the proposed revised Preamble (Annex 2) and that the important points of paragraphs 1-5 of the "General Principles" are incorporated into the proposed revised text. It is also of note that the "General Principles" was adopted as advisory text by the CAC in 1972, 20 years before the CAC shifted its focus away from the development of commodity-based standards to general subject standards. Thus, this original advisory text was intended as guidance to commodity committees when elaborating food additive provisions in their standards. Therefore, we propose that the CCFAC recommend that the CAC revoke the Codex General Principles for the Use of Food Additives (CAC/Misc.-1972), as this document is no longer necessary.

Recommendation no. 3 (Paragraph 44): that **"**the CCFAC takes due note of the recommendation made to it by the Codex Alimentarius Commission at its 23rd Session (1999) which states that "prior to its publication, the General Standard should take into account the endorsed food additives provisions contained in Codex Commodity Standards."

The statement by the 23rd CAC (ALINORM 99/37, para. 109) was not a recommendation. Rather, it was a confirmation of an earlier agreement. The elaboration of the GSFA from its inception has taken into account the additive provisions in commodity standards and continues to do so.

Section 2: Accompanying Document to the Codex GSFA

Recommendation no. 1 (Paragraph 83): that the title of the electronic version of the Preamble to the GSFA, accessible on the Codex website, be amended by adding the words "Preamble to the". We agree and have also included these words in the title of the revised Preamble (Annex 2).

Recommendation no. 2 (Paragraphs 84 and 85): make recommendations for editorial changes to the titles of Annexes A and B of the electronic version of the Preamble. We support the recommendations.

Recommendation no. 3 (Paragraph 86): that the status of List A (alphabetized list of the additives (including synonyms) in the GSFA with their JECFA-assigned ADIs and INS numbers) and List B (index of the additives arranged by INS number with their JECFA ADIs) be clarified as to whether they are subsections of Annex C or are stand alone texts.

We understand that the electronic version of these Lists has led to some confusion. As can be seen in the proposed revised Preamble (Section 6; see Annex 2), the GSFA consists of three main components:

(a) Preamble with three Annexes (A, B, and C).

(b) Food Additive Provisions (Tables 1, 2 and 3(with Annex))

(c) Index of Additives Listed in the Standard (Lists A and B)

The United States recommends that the CCFAC requests that the Codex Secretariat revise as necessary the titles of the Annexes and Tables to conform to the above.

Paragraph 86 also notes that "the first section of the electronic version of List A is missing the INS and ADIs next to the additive name." List A of the Index includes both the primary name (i.e., "Main term") for the additives in the GSFA (upper-case font) and synonyms (lower-case font), as stated in the subtitle. The JECFA ADIs and the INS numbers were intentionally associated only with the primary names listed in the first column. Synonyms are not included in List B.

Lists A and B require updating. The United States believes that updating these lists is not trivial. Furthermore, these lists need to be maintained as revisions to the GSFA (e.g., changes in ADIs) continue to be made. As all information contained in these lists is now accessible electronically through the Codex and JECFA websites, we recommend that the CCFAC consider the elimination of these two lists from the GSFA.

Recommendation (Paragraph 91): that "Paragraph 2 of the Preamble [to the GSFA] be amended to include a definition for 'widely used' as well as all other terms and definitions used in the GSFA."

The expression "widely used" (*viz*. "widely permitted for use") appears in the Procedural Manual's chapter on "Relations between Commodity Committees and General Committees," which gives guidance to commodity committees for elaborating the food additive provisions in standards subject to their terms of reference. The term "widely used" (or "widely permitted") does not currently appear in the Preamble. Although the 35th CCFAC (ALINORM 03/12A, para. 43) requested a definition for "widely used," no definition or language that would incorporate the term in the Preamble was offered in the discussion paper. Also, the discussion paper did not identify other terms in the Preamble that may require defining.

The United States recommends that the CCFAC not endorse this recommendation. As noted in the discussion paper (paragraph 88), the term "widely used" has been "questioned on several occasions when Member States recommend additive use and maximum levels within a commodity whose production is restricted to regional trade or is produced in limited volume." We believe the term "widely used" is not easily defined and attempts to do so would engender protracted and unproductive discussions. Further, we see no advantage or utility for the promotion of consumer protection or fair trade practices by providing a definition for "widely used." We believe that amending the Procedural Manual to eliminate the phrase "widely used" (i.e., "widely permitted for use") is the sensible solution. Therefore, rather than amending "Paragraph 2" (i.e., Section 1.2) of the Preamble to the GSFA as proposed, the United States recommends revision of the section *Food Additives and Contaminants* of the Procedural Manual to reflect the current focus of the CAC on the development of science-based horizontal standards that protect consumer health and ensure fair trade practices. A proposed revision to the Procedural Manual is given in Annex 1.

Section 3: Review of the Policy for Selecting Maximum Levels of Use for Inclusion in the GSFA

Recommendation no. 1 (Paragraph 108): that "with respect to Codex Standardized Commodities, the GSFA should only list the food additives contained in Codex Standards based on the endorsement of these food additives by the CCFAC."

In effect, this recommendation proposes that all food additive provisions developed by commodity committees be listed separately from their provisions for use in non-standardized foods. Implementation of this recommendation would make it extremely difficult, if not impossible, to develop estimates of intake for use in any risk assessment that may be required. Such an approach would also undermine the intent of the GSFA as a true horizontal standard, covering both standardized and non-standardized foods, and result in a return to the practices of Codex before 1990, which focused on the elaboration of vertical standards containing extensive lists of additive provisions. The United States recommends that the CCFAC not endorse this recommendation.

Recommendation no. 2 (Paragraph 111): that "the following text be included in the Preamble:

i. the lowest reported level of use is taken as the starting point for discussion

ii. If a Codex Member considers that the proposed Maximum Level of use of a food additive is too low, then this Codex Member should provide data proving that the proposed ML of use is technologically insufficient and that a higher proposed ML of use would not present a risk to the health of the consumers and that it would not lead to consumer deception about the nature of the food. It should be ensured that the data is based on foods which are identical or equivalent."

The proposed text contradicts the CCFAC's decisions on the principles to simplify the draft standard, made during its 28th (1996) and 29th (1997) sessions (CX/FAC 03/6, paras.15-17), that the initial entries into the draft GSFA for each food category would be the highest maximum reported use level, *taking into account maximum levels for additives in both standardized and non-standardized foods.* The CCFAC decided that these maximum levels were to be the starting point for discussions. If CCFAC were to agree to implement the proposed recommendation, the draft GSFA would require either complete dismantling and reconstruction from the raw data or starting over and again collecting additive use information from Codex member countries – substantial undertakings that would significantly impede the elaboration of a general standard for food additives.

The proposed text also stands in opposition to the 30th (1998) CCFAC's decision agreeing to procedures to resolve questions regarding whether a proposed GSFA maximum use level for an additive in a specific food category is justified (see CX/FAC 03/6, para. 48). The CCFAC had agreed that if a Codex member country considers a proposed maximum level to be too *high*, data should be presented to demonstrate that the level presents a risk to public health, might lead to consumer deception, or is otherwise technologically unnecessary. This procedure is based on the underlying principles of the GSFA (see Annex 2) that the maximum use levels in the standard are safe and that additive use must be in accordance with GMP, including use at the lowest level necessary to achieve the intended technical effect.

The United States does not support this recommendation.

Recommendation no. 3 (Paragraph 112): that "the Food Categorization System reference the Codex Standard which regulates the particular foodstuffs."

The intent of this recommendation is to provide users of the GSFA with an awareness "of the existence of the two lists of food additives". A suggestion for making such a "reference" is not offered. Annex C to the Preamble of the GSFA provides the necessary cross-references between the commodity standards and the GSFA Food Category System. Furthermore, the Codex Secretariat is developing an electronic version of the GSFA that should allow the user to toggle between the GSFA and the food additive provisions section of the commodity standards. The United States fails to see the utility of the recommendation and does not support it.

COMMENTS ON SECTION 2.3: STEP-BY-STEP APPROACH TO THE USE OF THE GSFA

Section 2.3 of the discussion paper (paragraphs 92-102) is a reasonable first attempt toward developing a user's guide for the GSFA. However, the discussion is limited to the determination of which food additives in the GSFA are acceptable for use in foods subject to a particular commodity standard. The paper fails to recognize the diversity of users of the GSFA and the variety of information they may seek from the GSFA. For example, the discussion paper provides no guidance on users seeking information to address questions such as "In which foods may additive X be used?" or "For food X, which additives with functional effect Y are acceptable?" Before moving forward with this user guide, the CCFAC must first consider more broadly the users of the GSFA and the information they expect the standard to provide.

We believe it useful to briefly note some inaccuracies and misunderstandings that we have identified in Section 2.3. For example:

1) The term "recommended" (para. 92) is inappropriate, as the GSFA does not "recommend" a level. The level indicated is the acceptable maximum level under conditions of safe use.

2) The reference to "commodity" (paras. 93, 95-97) is misleading. The term should be "food." The use of "commodity" implies that the GSFA food category system and GSFA apply only to foods standardized by commodity committees, which is not so.

3) Paragraph 99 is not a "step." It is a description of Table 3.

4) Paragraph 100, 2nd bullet, should read "… (with and without **numerical** ADIs)…"

REVISION OF THE PREAMBLE TO THE GSFA AND THE PROCEDURAL MANUAL

Proposed revisions to the Preamble and the Procedural Manual were previously expressed in paragraph 100 of CX/FAC 03/6. The United States agrees that it is timely and appropriate for CCFAC to undertake this work and offers Annexes 1 and 2 for further consideration by the committee. Annex 1 proposes revisions to three sections of the Procedural Manual: 1) Format and Content of Codex Standards; 2) Format for Codex Commodity Standards; and 3) Relations Between Commodity Committees and General Committees. Annex 2 contains a revised Preamble for the GSFA.

Key points with regard to proposed revisions of the Procedural Manual (Annex 1) include:

1) Introduction of a statement that the food additive sections of commodity standards reference the GSFA, unless there is a need to do otherwise;

2) Introduction of a statement that food additive sections of commodity standards reference the relevant food category titles and numbers in the GSFA and, as appropriate, the additive functional classes that are technologically justified; and

3) Deletion of the provision that the food additive sections of commodity standards include the individual names of the additives permitted and references to the maximum amount permitted in the food.

Significant proposed revisions to the Preamble (Annex 2) include:

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

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

3) A new Section 3.5 that addresses the CCFAC's agreement on the principles for establishing maximum levels for the use of food additives (ALINORM 03/12A, para. 44).

4) Clarification of the format of the GSFA.

5) A change in all references to permitted food additives, permitted levels, permitted maximum levels, and maximum permitted levels to acceptable food additives, acceptable levels, acceptable maximum levels, and maximum acceptable levels, respectively.

Point 5, regarding the replacement of "permitted" by "acceptable," was recommended in CX/FAC 03/6 (paragraph 83 (c)). Paragraphs 68-70 of CX/FAC 03/6 provided a rationale for this recommendation, emphasizing: 1) the importance of distinguishing between a GSFA maximum use level and an optimum, recommended, or typical use level; and 2) the role that Codex standards play in providing sovereign states with guidance for crafting and implementing their national legislation, laws and regulations. The United States and other Codex members supported this recommendation (CX/FAC 03/6-Add. 1, and CRD 5).

Finally, it is our desire that the 36th CCFAC reach a consensus on how to address the issues of the relationship between the GSFA and commodity standards. This consensus should be consistent with the CAC's mandate to its subsidiary bodies to focus on the elaboration of horizontal standards while revising the commodity standards by minimizing their provisions to essential quality factors. We look forward to working with our CCFAC colleagues to find a common understanding of the relationship between the GSFA and the commodity standards and to reach a consensus on the necessary revisions in relevant Codex documents (GSFA Preamble, Codex Procedural Manual, commodity standards) to implement a consistent approach throughout Codex.

ANNEX 1

Food Additive Sections of Procedural Manual (13th Edition)

(Bold font is <u>new</u> text)

<u>FORMAT AND CONTENT OF CODEX STANDARDS</u>

Page: 38

Food Additives

16. The food additives included in the standard have been assessed **for their safety** and cleared by JECFA. The Commodity Committee and the CCFAC have assessed technological need and safety in use. If national laws are different, all the detailed differences should be reported. It should be borne in mind, however, that the aim of international food standardization work is to harmonize policies and attitudes as much as possible. Therefore every effort should be made to keep deviations to the minimum.

<u>FORMAT FOR CODEX COMMODITY STANDARDS</u>

Page 91:

Food Additives

This section should refer to the General Standard for Food Additives (CODEX STAN 192), unless there is a need to do otherwise. When a Codex commodity committee is of the opinion that the provisions of the General Standard for Food Additives are not applicable to one or more of its standards, the commodity committee may request the Codex Committee on Food Additives and Contaminants to endorse deviations from the General Standard for Food Additives.

This section should refer to the appropriate food category title and number in the General Standard for Food Additives, and, where appropriate, to the technologically justified additive functional classes. The names of additives, their INS number, and their acceptable maximum use levels generally should not be incorporated into a Codex commodity standard.

~~This section should contain the names of the additives permitted and, where appropriate, the maximum amount permitted in the food. It should be prepared in accordance with guidance given on page 84 and may take the following form:~~

~~*"The following provisions in respect of food additives and their specifications as contained in section ..... of the Codex Alimentarius are subject to endorsement [have been endorsed] by the Codex Committee on Food Additives and Contaminants."*~~

~~Then should follow a tabulation, viz.:~~

~~*"Name of additive, maximum level (in percentage or mg/kg)."*~~

<u>RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL COMMITTEES</u>

Page 94:

Codex Committees may ask the advice and guidance of committees having responsibility for matters applicable to all foods on any points coming within their province.

The Codex Committees on Food Labelling; Food Additives and Contaminants; Methods of Analysis and Sampling; Food Hygiene; Nutrition and Foods for Special Dietary Uses; and Food Import and Export Inspection and Certification Systems may establish general provisions on matters within their terms of reference. These provisions should only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise.

Codex commodity standards shall contain sections on hygiene, labelling and methods of analysis and sampling and these sections should contain all of the relevant provisions of the standard. Provisions of Codex General Standards, Codes or Guidelines shall only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise. Where Codex Committees are of the opinion that the general provisions are not applicable to one or more commodity standards, they may request the responsible Committees to endorse deviations from the general provisions of the Codex Alimentarius. Such requests should be fully justified and supported by available scientific evidence and other relevant information. Sections on **food additives, contaminants,** hygiene, labelling, and methods of analysis and sampling which contain specific provisions or provisions supplementing the Codex General Standards, Codes or Guidelines shall be referred to the responsible Codex Committees at the most suitable time during Steps 3, 4 and 5 of the Procedure for the Elaboration of Codex Standards and Related Texts, though such reference should not be allowed to delay the progress of the standard to the subsequent steps of the Procedure.

Subject and commodity committees should refer to the principles and guidelines developed by the Codex Committee on Food Import and Export Inspection and Certification Systems when developing provisions and/or recommendations on inspection and certification and make any appropriate amendments to the standards, guidelines and codes within the responsibility of the individual committees at the earliest convenient time.

[FOOD LABELLING]

FOOD ADDITIVES AND CONTAMINANTS

Codex commodity committees should prepare a section on food additives in each draft commodity standard and this section should reference the Codex General Standard for Food Additives (CODEX STAN 192). Exemptions from, or additions to, the General Standard for Food Additives that are necessary for its interpretation with respect to foods subject to the commodity standard should be justified fully to the Codex Committee on Food Additives and Contaminants and should be restricted as much as possible with regard to the specified applications. Information specified in each Codex commodity standard should be limited to the following:

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

As appropriate, commodity standards may state the relevant food additive functional classes, as described in the Codex International Numbering System for Food Additives (XOT 04), that are technologically needed in a standardized food. Commodity committees may also prepare a working paper for consideration by 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. It should be noted that these maximum use levels are not necessarily the maximum safe levels of use; these are established by the Codex Committee on Food Additives and Contaminants and incorporated into the Codex General Standard for Food Additives. Commodity committees are responsible for establishing the technological need for all additive provisions in standards elaborated under their terms of reference.

~~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.~~

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 in commodity standards ~~will require to~~ **shall** be endorsed by the Codex Committee on Food Additives and Contaminants**.** ~~, on the basis of technological justification submitted by the commodity committees~~ **Endorsements should be based on information provided by commodity committees on technological need, technological function, and technologically justified levels of use of the food additive in foods subject to the commodity standards** and on ~~of~~ the recommendations of the Joint FAO/WHO Expert Committee on Food Additives **(JECFA)** concerning the safety-in-use (acceptable daily intake (ADI) and other restrictions), ~~and~~ **including** an estimate of the potential and, where possible, the actual intake of the food additives, **thus** ensuring conformity with the General ~~Principles~~ **Standard** for ~~the Use of~~ Food Additives.

In preparing working papers for the Codex Committee on Food Additives **and Contaminants**, 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 **contained in the Preamble to the Codex General Standard for Food Additives. Food additive provisions for endorsement by the Codex Committee on Food Additives and Contaminants** ~~Provisions for food additives~~ should indicate the International Numbering System (INS) number, the ADI, **and technologically justified levels of use.** ~~, 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**, including the General Principles for the Use of Food Additives contained therein**. 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.

Good Manufacturing Practice 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.

ANNEX 2

PREAMBLE TO THE GENERAL STANDARD FOR FOOD ADDITIVES

CODEX STAN 192-1995, Rev. ~~3-20014~~-200X

1. SCOPE

1.1 ~~PERMITTED~~ ACCEPTABLE FOOD ADDITIVES

Only the food additives listed herein are ~~permitted~~ **acceptable** for use in foods in conformance with the provisions of this Standard.[1] Only food additives which have been **assigned an Acceptable Daily Intake (ADI)** ~~evaluated~~ by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) **and an International Numbering System (INS) designation by Codex** ~~and found acceptable for use in foods~~ are included in this Standard. **The use of additives in conformance with this standard is considered to be technologically justified.**

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 Standards and this standard. The food additive provisions of Codex Commodity Standards shall be included in and superseded by the provisions of this Standard. Codex Commodity Committees have the responsibility to establish the technological need for the use of additives in foods subject to a commodity standard. The recommendation by the commodity committees may also be taken into account when considering food additive provisions for similar non-standardized foods.

~~This Standard sets forth the conditions under which permitted food additives may be used in all foods, whether or not they have previously been standardized by Codex. The food additive provisions of Codex Commodity Standards shall be included in and superseded by the provisions of this Standard. These provisions also comply with the other requirements of the Preamble.~~

~~1.3 FOODS IN WHICH ADDITIVES MAY NOT BE USED~~

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

1.~~4~~3 THE ~~PERMITTED~~ ACCEPTABLE MAXIMUM LEVELS OF USE FOR FOOD ADDITIVES

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

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

~~The Danish budget method~~**Annex A of this Preamble** may be used as a first step in this regard.~~[2]~~ The ~~submission~~ **evaluation** of actual food consumption data is also encouraged.

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

~~[2] "Consensus Document on the Danish Budget Method", Nordic Working Group on Food Toxicology and Risks Evaluation, Report No. 4/90.~~

The acceptable maximum level of use for a food additive established by this standard is the maximum safe level of use of the additive in a food product within the food category described under limited conditions of intake. In order to conform to this standard, the quantity of the additive actually added to food shall be at or below the acceptable maximum level, be based on national intake assessments and be used in accordance with GMP, which includes use at the lowest level necessary to achieve the desired technical effect.

2. DEFINITIONS ~~OF TERMS USED IN THIS STANDARD~~

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

b) ***Acceptable Daily Intake (ADI)*** is an estimate by JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk ~~(standard man = 60 kg)~~.[4]

c) ***Acceptable Daily Intake "Not Specified" (NS)***[5] is a term applicable to a food substance of very low toxicity which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food does not, in the opinion of JECFA, represent a hazard to health. For that reason, and for reasons stated in individual JECFA evaluations, establishment of an acceptable daily intake expressed in numerical form is not deemed necessary by JECFA. An additive meeting this criterion must be used within the bounds of good manufacturing practice as defined in ~~subparagraph~~ **section** 3.3 below.

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

3.1 FOOD ADDITIVE SAFETY

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

~~b)~~ The inclusion of a food additive in this Standard shall have taken into account any ~~Acceptable Daily Intake~~**ADI**, or equivalent assessment, established for the additive by JECFA and its probable daily intake[7] from all sources. Where the ~~food~~ additive is to be used in foods eaten by special groups of consumers, account shall be taken of the probable daily intake of the ~~food~~ additive by **those** consumers. ~~in those groups.~~

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[3] Codex Alimentarius Procedural Manual

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

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

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

[7] **"**Guidelines for Simple Evaluation of Food Additive Intake", CAC/VOL. XIV Ed. 1, Supplement 2 (1989), gives procedures for calculating the theoretical maximum daily intake (TMDI) and the estimated daily intake (EDI) of food additives; other appropriate procedures may be used to calculate the TMDI and EDI.

c) **The quantity of an additive added to food is at or below the acceptable maximum level based on the intake assessment of the individual Codex member country and the lowest level necessary to achieve the intended technical effect.**

3.2 JUSTIFICATION FOR THE USE OF ADDITIVES

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

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

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

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

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

3.3 GOOD MANUFACTURING PRACTICE (GMP)[8]

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

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

b) the quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and,

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

3.4 SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES

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

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

[9] ~~Food additive specifications endorsed by the Codex Alimentarius Commission are included in the JECFA "Compendium of Food Additive Specifications," Volumes 1 and 2 (1992) and in addenda thereto, published by FAO.~~ **An index (CAC/MISC 6 – 2001) of all specifications adopted by the Codex Alimentarius Commission, as well as their year of adoption, is available by accessing the Codex website. These specifications, prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), are also being published in the FAO Food and Nutrition Paper series as the "Compendium of Food Additive Specifications," which consists of two volumes published in 1992 and a subsequent series of addenda. The specifications are also available at the JECFA website. However, neither this website nor the addenda to the Compendium contain information that shows which specifications have been adopted by Codex.**

3.5 PRINCIPLES FOR THE ESTABLISHMENT OF ACCEPTABLE MAXIMUM USE LEVELS IN THE GSFA

When establishing acceptable maximum levels for the use of food additives, the following principles should be applied:

- **Additives assigned a numerical ADI by JECFA should be assigned a numerical acceptable maximum level of use in the GSFA.**
- **Additives assigned a non-numerical ADI by JECFA should be assigned a use level of "GMP" in the GSFA, *in lieu* of a numerical acceptable maximum level.**

However, exceptions to these principles may be appropriate in some cases.

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

4.1 COMPLIANCE WITH THE CARRY-OVER PRINCIPLE

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

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

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

c) the food into which the additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the ingredients under proper technological conditions or manufacturing practice.

4.2 INGREDIENTS AND RAW MATERIALS AS CARRIERS FOR ADDITIVES[11]

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

5. FOOD CATEGORY SYSTEM[12]

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

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

The food category system is based on the following principles:

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

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

[11] See ALINORM 97/12, para. 44.

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

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

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

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

6. FORMAT OF THE STANDARD

This Standard consists of three main components:

(a) Preamble with three Annexes.

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

ii. Annex B is a description of the Food Category System used to develop and organize Tables 1, 2, and 3 of the Standard.

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

(b) Food Additive Provisions

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

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

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

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

(c) Index of Additives Listed in the Standard

i. List A is an alphabetized list of the additives (including synonyms) in the Standard with their JECFA-assigned ADI and their INS number.

ii. List B is arranged numerically by additive INS number and includes the JECFA ADIs.

~~The food additives listed herein have been grouped into the 23 major functional classes of the Codex International Numbering System (INS) for Food Additives.[13]~~

~~Table 1 of this Standard specifies, for each food additive or food additive group (in alphabetical order), the foods in which the additive is acceptable for use, together with the acceptable maximum use levels. Table 1 also includes the uses of those additives with non-numerical ADIs for which a maximum use level is specified.~~

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

~~[13] Although the General Standard as currently drafted covers only antioxidants and preservatives, the complete Standard will eventually cover the uses of food additives in all 23 INS functional classes; see Codex Alimentarius Vol. 1A, Second Edition (Revised 1995), Section 5.2, pp. 57-92.~~

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

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

~~Table 1, 2 and 3 do not include reference to the uses of substances as processing aids.~~

Unless otherwise specified, **acceptable** maximum **use** levels for **the food additives in Tables 1 and 2** ~~food additives~~ are set on the final product as consumed. **Tables 1, 2, and 3 do not include references to the use of substances as processing aids[14].**

7. REVIEW AND REVISION OF THE STANDARD

7.1 REVIEW

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

7.2 REVISION

The food additive provisions of this Standard shall be amended as necessary. Proposed revisions ~~of this Standard~~ may be initiated by recommendations by Codex Committees, Codex member States, or the Codex Alimentarius Commission. Information to support amendment of this Standard shall be provided by the proposing body. Supporting information that shall be provided to the Codex Committee on Food Additives and Contaminants may include, as appropriate:

- Specifications for the food additive;

- **Summary of JECFA safety evaluation of the food additive;**

- Intended food category or sub-category**;** ~~, and use level for the food additive~~;

- ~~Summary of JECFA safety evaluation of the food additive; and~~

- Technological justification and need for the additive**; and**

- **The acceptable maximum use level for the food additive.**

The Codex Committee for Food Additives and Contaminants shall consider all proposed amendments to this Standard.

FEDERATION OF FOOD ADDITIVES AND FOOD ENZYMES INDUSTRIES (ELC):

Section 1.3 Recommendations on the relationship between CCFAC and the Commodity standards

ELC agrees with Recommendation 3 which proposes that prior to its publication the GSFA should take into account the endorsed food additive provisions contained in the Codex Commodity standards. However, ELC stresses that this should not prevent that the GSFA regulates the use of additives in non-standardised foods.

Section 2.1 Numerical ADIs and numerical limitation of use

Paragraphs 66 and 67 mention that CCFAC 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. However, exemptions are allowed where the CCFAC agrees on a case-by case basis.

ELC would like to comment as follows to these two paragraphs:

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[14] Processing Aid means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product. Codex Alimentarius Commission, Procedural Manual, ~~Tenth Edition (1997), p. 44.~~

ELC believes that the QS/GMP principle has important advantages for consumers, regulators and industry alike and must be retained as the GSFA moves toward final adoption within Codex, in particular for additives with high numerical ADIs.

The Preamble in the General Standard defines GMP as the manufacturing practice under which the quantity of an additive used in a foodstuff *"shall be limited to the lowest possible level necessary to accomplish its desired effect"*. In many cases the use of additives is technologically self-limiting. In our view, GMP remains therefore entirely appropriate for those additives even if they have a numerical ADI. This is the case for example for emulsifiers and sweeteners.

Recommendation by ELC

ELC calls on the Codex member countries to reaffirm the role of GMP in the GSFA for additives with numerical ADIs, which are unlikely to be exceeded.

SECTION 2.2 ' Widely used'

SECTION 2.2 addresses 'Definitions and terminology used in the GSFA'. CCFAC decided at its 35th session last year that the term 'widely used' should be defined.

ELC believes that in the past CCFAC agreed that it is necessary to establish that at least two Codex Member States permit the use of the additive. This establishes that trade may occur in the food containing the additive.

Technological need may differ from one country to another and also with time. Even limited use of a food additive, geographically or in a number of food products or in amounts added to food, are all justifiable reasons for inclusion in the GSFA.

Recommendation by ELC

These factors should be taken into account when the term 'widely used' is defined.

SECTION 3 Maximum levels of use

ELC would like to comment on SECTION 3 of the paper and the recommendations for a review of the policy for selecting maximum levels of use for inclusion in the GSFA.

Recommendation 2 suggests that the lowest reported level of use is taken as the starting point for discussion and that it is the responsibility of governments wishing to establish a higher level to justify such use.

Recommendation by ELC

ELC recommends that the levels should cover all uses of the additive rather than just be the lowest reported level. The establishment of maximum levels of use should be based on data and information (on climate, technology, transport, consumer expectations) provided by all regions of the world and this information would be used in the development of the Standard.

Not in all countries industry will need to use the maximum level but only as much as is needed to achieve the desired effect.

INSTITUTE OF FOOD TECHNOLOGISTS (IFT):

The Institute of Food Technologists (IFT) is pleased to have this opportunity to provide comments on CX/FAC 04/36/6, *Proposed Draft Preamble of the Codex General Standard for Food Additives*, which will be considered at the thirty-sixth Session of the Codex Committee on Food Additives (CCFAC), March 22-26, 2004.

IFT is an international scientific society with 27,000 individual members working throughout the food science and technology profession. IFT's mission is to advance the science and technology of food through the exchange of knowledge.

IFT supports the practices that are currently used to develop the General Standard for Food Additives (GSFA). The food additives and their maximum levels of use in the GSFA are based on the food additive provisions of the Commodity Standards or the requests of Member Countries. The General Principles for the Use of Food Additives in the Preamble to the GSFA require that the food additives must have been evaluated by JECFA, be safe at the levels of use proposed, serve one of more of the technological functions established by Codex, not mislead the consumer, and be used according to good manufacturing practice, among other requirements. These requirements and practices have been adopted by the Codex Alimentarius Commission and reflect the purpose of the Commission—to protect the health of the consumers and ensure fair practices in the food trade.

IFT does not support the adoption of unnecessarily restrictive approaches to listing additives in the GSFA. Many developments have been made in food technology to improve the nutritional quality, safety, and stability of foods. Many of these advances have been made to address the specific situations and technological needs of different countries, such as the availability of raw materials and climatic conditions. These advances in food technology have resulted in increased availability and affordability of food in many parts of the world. Restricting the listing of these food additives for reasons that do not relate to the health of the consumer would not be appropriate.

IFT has the following comments on the recommendations in the Proposed Draft Preamble of the Codex General Standard for Food Additives.

Section 1: Review of the Preamble to the General Standard for Food Additives

Recommendation No. 1

IFT does not support the recommendation to request the Commission to clarify the relationship between the CCFAC and the Commodity Commodities with regard to food additive allocation for standardized foods. There have already been many discussions on this topic. It has been considered in CCFAC, the Committee on General Principles, and the Commission. These discussions resulted in decisions that the food additive provisions of Codex Commodity Standards shall be included in and superseded by the provisions of the GSFA and the additives section of the Commodity Standards shall be included as an integral part of Codex Standards until such time as the GSFA is finalized. Amendments were also made to the Procedural Manual as a result of these discussions. IFT therefore believes that another discussion on this topic is not necessary.

Recommendation No. 2

IFT does not support Recommendation No. 2—to include the language from Paragraph 6 of the General Principles for the Use of Food Additives from Volume 1A of the Codex Alimentarius in the GSFA Preamble. These concepts are already covered in the General Principles for the Use of Food Additives in the Preamble to the GSFA.

Recommendation No. 3

IFT does not believe that Recommendation No. 3 is necessary because the GSFA already includes the additives from the Commodity Standards.

Section 2.2: Definitions and Terminology Used in the GSFA, Paragraph 2 of the Preamble

Recommendation to Define "Widely Used" and other Terms and Definitions

IFT does not support the recommendation that Paragraph 2 of the Preamble be amended to include a definition for "widely used" or other terms and definitions used in the GSFA.

The recommendation of the Working Group is based on text from the Procedural Manual for the inclusion of food additives in Codex Commodity Standards. One of the criteria listed in the Procedural Manual for Codex states, “The section [on food additives in each draft Commodity Standard] 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." IFT interprets this statement to mean that if an additive is not considered to be technologically necessary, it can be included in a Commodity Standard if it is widely permitted**.**

This is not an alternative for inclusion of an additive in the GSFA. One of the requirements for including food additives in the GSFA is technological justification. The Committee has already agreed that a Member Country's submission of the use of an additive serves as justification for technological need, and this decision is reflected in wording in the Preamble. In addition, the food additives in the GSFA must have been evaluated by JECFA, be safe at the levels of use proposed, serve one or more of the technological functions established by Codex, not mislead the consumer, and be used according to good manufacturing practices.

If a food additive meets the above criteria, IFT does not see the need for a criterion such as "widely used" and does not support including a definition in the GSFA.

Section 3: Review of the Policy for Selecting Maximum Levels of Use

Recommendation No. 1

IFT does not support Recommendation No. 1 that, with respect to the Codex Standardized Commodities, the GSFA list only the food additives contained in Codex Standards. The document provides no evidence that the GSFA as currently being developed presents a risk to the health of consumers.

Recommendation No. 2

IFT does not support recommendation No. 2. We believe that the highest level should be the starting point for the discussion. Even the Working Group accepts the basic tenets that the technological needs for food additives differ from country to country, partly due to the availability of raw materials, the climate, the advancement of the food technology used in production, and other factors (para. 103). Further, the good manufacturing provisions of the Preamble dictate that the quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect.

If a Codex Member Country considers that the proposed Maximum Level of use of a food additive is too high, that Member Country should provide data proving that the proposed level of use is too high for the use and conditions proposed and that it presents a risk to consumer health.

The Member Country(s) proposing the level would have the opportunity to respond to the data.

Recommendation No. 3

IFT does not support the recommendation that the Food Categorization System reference the Codex Commodity Standards. As stated above, and many times by the Working Group, the Preamble to the GSFA states that the food additive provisions of the Commodity Standards shall be included in and superseded by the GSFA. There would therefore be no reason to reference the Commodity Standards.

Summary

In summary, IFT believes that the practices and procedures currently used to develop the General Standard for Food Additives (GSFA) provide for the protection of consumer health and ensure fair practices in food trade, and permit the use of additives at levels necessary under the different conditions in the Member Countries.

INTERNATIONAL FEDERATION OF FRUIT JUICE PRODUCERS (IFU):

Our Federation, which represents the global fruit juice industry, would like to comment the above mentioned document, taking in account the experience of establishing the new Codex Standard for Fruit Juices and Nectars.

Without going into details of the text, our organisation welcomes all regulatory measures which solve the problem of inconsistencies between the list of additives in the Draft Codex Standard for Fruit Juices and Nectars and the GSFA. It is absolutely unacceptable for the worldwide fruit juice industry, that additives are in the GSFA, which are not needed, for which there is no technological justification and which would cause serious damage to the image of fruit juices as natural products.

For us it is indispensable that the commodity committee, taking into account the need of all member countries when establishing the list of additives including their max. use level, decides finally about the additives as well as their max. use level which should be allowed in the respective commodity. These additives have then to be taken over to the GSFA and all other additives, listed in the GSFA for this commodity, have to be deleted.

Self evident only additives and levels, which are adopted by JECFA, can be listed.

We are fully aware, that this modifies some principles of the GSFA, but we are convinced that at the end this will be positive for the GSFA, as the users will find the same additives in the GSFA and in the commodity standard.

INTERNATIONAL SOFT DRINKS COUNCIL (ISDC):

General

ISDC is concerned that the report is **not a consensus report** and thus provides a limited viewpoint of a select group of member countries and NGOs, mostly from the European region. A more objective report would present a broader viewpoint with arguments in support of each view.

SECTION 1

1.3 RECOMMENDATIONS

Recommendation 1 (para 42)

Rather than requesting the Commission to clarify the relationship between the CCFAC and the Commodity Committees concerning food additive allocation for standardized foods, there should be further discussion and consensus on this issue at the CCFAC. We agree with the statement in paragraph 39 of the document in that only the technological function of the food additive be required in the commodity standard rather than a list of specific additives. This would provide the necessary flexibility in product formulations and would eliminate the need to revise a commodity standard every time a new food additive is approved. We suggest that CCFAC consider this approach that would eliminate the need for this recommendation and remove the inconsistencies between the commodity standards and the GSFA.

Recommendation 2 (para 43)

The General Principles for the Use of Food Additives are included as Section 3 of the Preamble and a reference is made to the General Principles for the Use of Food Additives (footnote 6). Therefore, ISDC questions the need to include paragraph 6 in Section 1.2 of the GSFA Preamble as proposed in the Report.

SECTION 2.1

RECOMMENDATIONS (paras 83-86)

These recommendations are editorial in nature and ISDC has no objection regarding the proposed actions.

SECTION 2.2

RECOMMENDATIONS (para 91).

It is recommended that the paragraph 2 (DEFINITIONS) of the Preamble be amended to include a definition for "widely used." We are uncertain where this term appears in the Preamble and do not believe that there is a consensus of its inclusion in the Preamble.

SECTION 3

RECOMMENDATIONS

Recommendation 1 (para 108)

The GSFA food categories are often broader than the standardized commodities and we do not agree with thisrecommendation.

Recommendation 2 (para 111)

ISDC strongly disagrees with this recommendation that would negate 10 years of progress in the GSFA. It is critical that Codex standards, recommendations, and guidelines be adequate to assure that the needs of all Codex countries are met. We would like to refer the following quote from CX/FAC 03/6 (paras 86 and 87) that ISDC fully supports:

> "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."

Recommendation 3 (para 112)

We have no objection indicating references to the Codex commodity standards in the Food Category System for standardized foods. However, this would become unnecessary if the commodity standards would list only the technological functions of food additives.