

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 6 (a)

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS**

Thirty-seventh Session

The Hague, the Netherlands, 25 – 29 April 2005

PREAMBLE OF THE GENERAL STANDARD FOR FOOD ADDITIVES (I)

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

COMMENTS

The following comments have been received from Brazil, Cuba, USA, European Community, ELC, IFT and IFU

BRAZIL:

Appendix I – Current Working Principles for Elaboration of the GSFA

III. Assembling the Draft Food Additive Provisions

1. Brazil would like a clarification whether acceptable ADI (eg shellac) is include under full ADI. If it is true, acceptable ADI should be included in the squares of Diagram (Appendix II).
2. Which is the procedure when an additive has a full ADI and a re-evaluation from JECFA, the additive has a temporary ADI? If the additive is withdrawn, which is the status provision (step)?

Eg.

| Additive | JECFA meeting |
|------------------|--|
| INS160 - Annatto | 26 th :0-0.065 mg/kg bw 61 st : 0 – 0,4mg/kg bw (temporary) |

Appendix II - Diagram

- 6th square: a) ADI not specified
We propose **ADI non-numerical**
- Between 7th and 8th square: we propose include **YES**
- 8th square: For each food category requested select the highest level of use
We propose: For each food category requested select the highest level of use **and include in Table 1 and Table 2 at Step 3.**

Appendix IV – Proposed Draft Revision

1.1 Food Additives Included in this Standard

We understand that the expression “equivalent safety assessment” is used for additives are not assigned an ADI but have been deemed “acceptable” for limited use. However, it is not so clear. We propose define “Acceptable ADI” and include under Section 2 “Definition”.

“Permitted” has been deleted, reminder this term is used on Table 1, Table 2 and Table 3.

1.3 Foods in which additives may not be used

Food categories or individual food items in which the use of food additives **listed in Table 3 or with non-numerical JECFA ADI** is not ~~allowed~~ acceptable or is restricted are defined by this standard.

We propose change the term allowed because Codex is not responsible for “approving” or “permitting” practices and procedures for food production.

2. Definitions

d) Maximum level of use:

We propose include on 4th line, after ...taking into account: **“raw materials”**

5. Food Category System

The food category system is a tool for ~~organizing~~ **assigning** ...

7. Review and Revision of the Standard

7.2 Revision

5th bullet:

- For additives with a numerical or **acceptable** ADI, a numerical...
- For additives with an ADI ~~not specified~~ **non-numerical** a recommendation to list the additive...

CUBA:

We are in agreement with the working principles for elaboration of the GSFA prepared by the working group led by China.

EUROPEAN COMMUNITY:

The European Community would like to thank the electronic Working Group and its chair China for the preparation of the documents regarding the revision of the Preamble and the outline of the current working principles, which will be subject to a separate working group meeting prior to the 37th CCFAC session.

The European Community would like to submit the following comments as regards these two items.

1. Proposed revision of the Preamble of the General Standard for Food Additives (paragraphs 14 to 28, Appendix IV)

The European Community would like to congratulate the electronic Working Group for the proposed revision of the preamble. The revision reflects well the many discussions that have been held in CCFAC during the last years. For example, it clarifies the role of the Commodity committees by stating clearly that they have the responsibility to provide technological justification for the use of the additives in standardised foods and further clarifies that CCFAC has the same responsibility for the use of the additives in non-standardised foods or foods where a Commodity committee no longer is in function (section 1.2). It also provides the guidance on what is meant as “technological need” by clarifying the section 3.2 “Justification for the use of the Additives” and what is to be understood with “maximum use level” by defining it in section 2 (d).

Furthermore, the proposed revision takes into account the necessity to carefully consider the use of food additives in foods for infants and young children by restricting the carry over principle in these food categories (section 4.3). This approach is also in line with that adopted by the Committee on Nutrition and Foods for Special Dietary Uses in the Codex Standard for infant formula (CODEX STAN 72-1981) and the draft revised standard for processed cereal-based foods for infants and young children (Alinorm 05/28/26 Appendix V).

The European Community is also satisfied to learn that the information provided by the petitioner for revision of the Standard (section 7.2) also contains consideration on the use of food additives for consumers, which is in fact in line with the requirements for the use of food additives laid down in section 3.2.

In conclusion, the European Community would like to support the revision of the Preamble as proposed.

2. Progress Report of the Working Group on the Working Principles of the GSFA (paragraphs 6 to 13, Appendices I, II and III)

The European Community would like to thank the electronic Working Group describing the current working principles on how the food additive provisions are entered in the General Standard on Food Additives. Especially the diagram laid down in Appendix II gives a good overview of the procedure. Now the focus should be on how to improve these current working methods in order to accelerate the completion of the Standard without jeopardising the safety of the consumers or creating unnecessary barriers to international trade.

During the elaboration of the GSFA there have been two major subjects for discussion: one on what is meant with technological need and how is this proven and the other on how to set the maximum use levels for additives.

The technological need has been considered proven just by the fact that a Member Country reports the use. The contradiction was noticed with the Commodity Standards where widely permitted use is referred to. It should be noted that the GSFA is elaborated to serve international trade. Therefore, the EC suggests that as long as the use of an additive fulfils one of the needs set out in section 3.2 of the Preamble and this is permitted in Member Countries from two or more Codex regions, the use in a given food or food category should be considered technologically justified without further justification.

The second item of long discussion has been how to set the maximum use level once the technological need in a food is established. Firstly the EC would like to note that it would be more beneficial to comment and discuss at one time on all the proposals for provisions for food additives for which a numerical ADI has been allocated whether they are at Step 3, at Step 6 or Step 5/8. This is due to the fact that the safe use of a food additive requires the understanding of the overall usage of the additive in question including the information on the already adopted provisions.

The current method of choosing the highest proposed level supported by two Member Countries has proven unsatisfactory as the levels are debated to the length. Even if the lowest reported levels were taken as a point of departure, the discussion would remain. This leads to frustration and to slowing down the development of the GSFA. It could be considered whether CCFAC should actually go into such detail when elaborating a standard. It seems very difficult to reflect all permitted uses of the world in one compromise Standard.

As any other standard, the GSFA will be subject to continuous revision, however, it is unfortunate that Table 1 and 2 are still incomplete. Therefore, in any case, the European Community urges the CCFAC to find a solution how GSFA can be completed in near future.

USA:

Appendices I and II

The United States generally supports these appendices as accurate descriptions of the process that the CCFAC has used to elaborate the GSFA. We believe that including these two appendices as part of the preamble of the GSFA would further the committee's work on the GSFA by improving the transparency of the process that the committee is following. Therefore, we propose that the 37th CCFAC agree to combine these two texts and include them as a new annex of the GSFA.

Appendix III and Paragraphs 6-13

The United States believes that Appendix III is useful in identifying and articulating in a clear and concise manner the inconsistencies among the Codex Procedural Manual, the preamble of the GSFA and the Codex General Principles for the Use of Food Additives (CAC/MISC 1-1972). We believe that this appendix will help focus the committee's deliberations on the relevant sections of these texts. However, we note that some inconsistencies between the GSFA and the general principles text are expected because the latter, adopted in 1972, reflects detailed guidance to commodity committees. Relevant portions of the general principles text, however, are incorporated into the GSFA preamble.

We offer the following additional comments.

Paragraph 8

The working group report observes that the general principles text is very specific with respect to the foods, conditions, and purposes for which a food additive may be used, and also notes that the GSFA refers to a food category system that is much less specific. The United States agrees that the GSFA's hierarchical food categories, with some exceptions, are more general (i.e., less specific) than the general principles text and Codex commodity standards. This is because the scope of the GSFA food categories is broader than most Codex commodity standards.

The hierarchical structure of the food category system greatly simplifies the additive tables by minimizing the number of food additive entries. The broader scope of the food categories is needed to accommodate standardized foods, their non-standardized counterparts, and the wide variety and diversity of non-standardized foods traded internationally with no standardized counterparts.

The organization of the GSFA's food category system is based on an assumption that foods produced with similar starting materials and processing have similar additive functional needs (e.g., antioxidant to prevent fat rancidity, emulsifier to maintain water/fat suspensions). The food category system allows for the consistent, systematic, and science-based assignment of a wide variety of similar foods in a minimum number of food categories, whether or not these foods are standardized.

Importantly, the food category titles do not confer any standardization to the name of the food as sold to the consumer. As a result, Codex is free to elaborate commodity standards with labelling criteria that promote fair trade practices and National authorities are free to implement labelling criteria to prevent economic adulteration and consumer deception.

The non-specific nature of the food category system is an asset and should be maintained. The urge to develop more specific food categories should be resisted as it could easily evolve into an endless task, especially if CCFAC's deliberations were to digress into debates over the definition of specific foods that reflect regional or national divergence in dietary preferences and consumer expectations. In our view, consumer expectations and regional or national diversity are better addressed through informative labelling, so that consumers can choose for themselves the products they prefer. Increasing the food category specificity will also undermine the purpose of the hierarchical structure of the food category system and will lead to an increase in the number of entries in the food additive tables. In our view, there would be no benefit, either for consumer health protection or for the promotion of fair trade practices, should the GSFA apply the more specific approach described in the principles text.

Paragraph 9

This paragraph identifies a significant difference between the general principles text and the preamble of the GSFA with respect to additive use levels. The general principles text uses the expression "lowest level necessary" whereas the preamble of the GSFA uses the expression "maximum levels". The United States notes that the terms of reference for the

CCFAC in the Codex Procedural Manual use the expressions "maximum level" and "guideline level" for additives. In addition, the section of the procedural manual, which contains guidance for food additives and contaminants to Codex commodity committees, uses the expression "maximum levels."

Section 3.3 of the preamble states: “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;....” Therefore, in our view, the significant difference between the general principles text and the GSFA preamble as described in paragraph 9 is not significant; it is a matter of context.

We note that the proposed changes to Section 3 of the GSFA preamble strengthen and clarify conformance to the food additive provisions in the GSFA, by including a new definition with interpretation of “maximum level of use” that relates to the application of good manufacturing practices for all additive uses (See para. 24 and Appendix IV of CX/FAC 05/37/7).

Paragraphs 10, 11, 12 and 13

The United States understands these paragraphs as pointing to significant differences among the Codex Procedural Manual, the GSFA preamble and the general principles text that focus on two fundamental inconsistencies in the Codex system. The first relates to the roles of commodity committees and the CCFAC in the elaboration of food additive provisions in commodity standards. The second relates to the relationship between the food additive provisions in commodity standards and the GSFA.

The United States recognizes that these are significant inconsistencies and we propose that the committee focus its future work on the text highlighted in these paragraphs once revisions to the preamble are agreed.

Appendix IV

The United States supports the proposed revisions to the GSFA preamble as contained in Appendix IV. We believe that these provisions improve the clarity of the preamble and thereby promote consistent interpretation of the standard as a whole. The United States supports advancing these revisions to the Codex Alimentarius Commission for adoption.

ELC:

ELC would like to thank the working group for the substantial work done for the preparation of this progress report. We appreciate to be given the opportunity to make comments on the proposed draft revision as provided in Appendix IV, in advance to the 37th session of CCFAC:

Section 1.2 Foods in which additives may be used

ELC agrees that the use of additives in standardised foods is subject to the conditions of use established by the Codex commodity standards and this standard. However, we insist that this should not prevent the GSFA to regulate the use of additives in non-standardised foods.

ELC is of the opinion that basis to appraise the technological justification, either by the commodity committees or by the CCFAC, needs to be clearly mentioned in the paper with reference to Section 3 “general principles for the use of food additives”.

Section 1.4 Maximum levels of use for food additives

ELC agrees on the change of terminology “maximum levels”, which is in line with the terminology used in EU legislation on food additives.

For effectiveness purpose, ELC supports the proposal of the working group that evaluation of actual food consumption data is encouraged, rather than a mere submission by member countries.

Section 3 General principles for the use of food additives

3.3 Good Manufacturing Practice

ELC welcomes that the role of GMP is reaffirmed in this section, since applying GMP principle is especially important for additives with numeric ADIs, which are unlikely to be exceeded.

New paragraph to be added after 3.3 and before 3.4: Technological justification

ELC would like to reiterate its proposal to include a new paragraph in the Preamble as a general principle for the use of food additives. **This new paragraph concerns the principles CCFAC used to decide on “technological justification”**. These are set out in the paper prepared by the USA (distributed with the e-mail on 2 August by the Chair of the working group). They could read as follows:

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

Approval of a food additive by a Member Country should, in the first instance, be taken as evidence of technological justification and need. Furthermore, in deciding how to include a provision in the GSFA, the committee may need to consider whether a use may be necessary only for a specific food or geographic region. (Argument ELC: Technological need may differ from one country to another and also with time. Even limited use of a food additive, geographically or in number of food products or in amounts added to food, are all justifiable reasons for inclusion in the GSFA.)

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

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

6. Description of the standard

ELC welcomes the proposed improvement related to a better description of the general structure of the Standard.

However, we believe that Table 1 should not be restricted to additives for which a maximum use is specified: as already mentioned, numerical ADIs should not necessarily mean numerical limitation of use: **possibility of use according to GMP should be maintained for additives with numerical ADIs which are unlikely to be exceeded.**

Also, ELC wonders whether it is appropriate to include as the footnote 26 the definition of processing aids as laid down in the CAC Procedural Manual. Actually, the current definition of processing aids has been questioned in the framework of the discussion paper prepared in 2002 by New Zealand (CX/FAC 02/9): the need to provide for a better definition in order to improve the distinction between processing aids and food additives was generally acknowledged. The 36th session of CCFAC agreed that further consideration should be given to processing aids in developing guidelines to address various aspects such as principles for their use and their control (Alinorm 04/27/12): it would probably be worthwhile to wait for the completion of this work before including a definition of processing aids in this document.

7. Review and revision of the Standard

Here again, in the 5th bullet point of section 7.2, ELC would suggest that reference to the application of GMP principle for additives with numerical ADIs, which are unlikely to be exceeded, is clearly mentioned.

ELC considers that the mention “by means of an exposure assessment” in the 6th bullet point of section 7.2 is redundant since criteria of section 3.1 already include “probable daily intake from all food sources”.

ELC would also appreciate to obtain clarification on the proposed request for “a reasoned statement that consumers will not be misled by the use of the additive”, e.g. what are the criteria to establish this reasoned statement.

IFT:

The Institute of Food Technologists (IFT) is pleased to have this opportunity to provide comments on CX/FAC 05/37/7, *Preamble of the General Standard for Food Additives-Progress Report of the Working Group on the Working Principles of the GSFA*, which will be considered at the thirty-seven Session of the Codex Committee on Food Additives (CCFAC), 25-29 April 2005.

IFT is an international scientific society with 26,000 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 commends the Working Group on the thoughtful approach to the revision of the Preamble. We believe that most of the revisions strengthen and clarify the Preamble; however, we suggest that the following language be added to the end of Section 3.1. c.

We believe the additional language will add clarity.

ADD to the end of Section 3.1.c): If neither JECFA nor the member country has an intake assessment, and the Annex A screen does not identify any safety concern, the requested maximum level shall be included in the GSFA.

IFU:

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

First of all we would like to state that most of the proposed amendments of the Preamble can be supported by our Federation. Nevertheless we have some comments.

Section 1.2

We take as granted, that the following principles are generally accepted:

- The commodity committees have the expertise to justify the technological necessity of an additive for the respective standardised food including its max. use level.
- The additive provisions of the standardised food and those of the GSFA have to be consistent, which means at the same time, that Table 2 of the GSFA for the respective food has to be identical with the additive provisions of the standardised food.

In the case of fruit juices and nectars and their concentrates, food categories 14.1.2.1, 14.1.2.3, 14.1.3.1 and 14.1.3.3, the problem of inconsistency has been solved at the 36th Session of CCFAC, as the committee agreed to delete the existing additives for the above mentioned food categories in the GSFA and to replace them by the additive provisions of the Draft Codex General Standard for Fruit Juices and Nectars.

But this situation is the exception within Codex. As an example the food category 0.2.2.1.1 “Butter and concentrated butter” containing 98 additives, is far away from being consistent with the Codex Standard for Butter (Codex Stan A-1-1971, Rev. 1-1999, Amended 2003), containing 10 additives.

The same procedure as in the case of fruit juices and nectars should apply to all additive provisions of standardised foods and should be stated clearly in the Preamble of the GSFA as an automatic process, as soon as CCFAC has finally adopted the additive provisions of the commodity committee. In case CCFAC does not agree with the provisions as forwarded by the commodity committee, CCFAC should not amend the proposed provisions but send it back to the commodity committee for reconsideration.

According to our opinion, Section 1.2 of the amended Preamble is not clear enough and the WG should revise the text at the WG meeting before the plenary CCFAC Session in April 2005.

Section 3.2d)

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

The above mentioned steps of the manufacture of a food are processing aids and not additives according to the definition of these substances in the Procedural Manual (13th edition, page 51). At least the words in italic have to be deleted.

Section 5a)

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

The exception *unless otherwise stated* has to be applied generally for food categories of standardised foods, as otherwise it would not be possible to fulfil the rules laid down for Section 1.2 in this comment.

Section 7.1

This section foresees the initiation of amendments of food additive provisions by Codex Committees, Codex member countries or the Codex Commission. We propose the addition of NGO's with observer status. It is likely that due to new technologies a food industry, organised in a NGO, sees the necessity for an amendment of the additive provisions of a food they are producing, and therefore this organisation should have the possibility to initiate a revision of the respective additive provisions.

This proposal would be in line with Appendix II: "Diagram of currently used procedure for additives proposed for entry into the GSFA", where observers are explicitly mentioned.

In an additional bullet it should be mentioned, that the commodity committee, responsible for the respective food category, for which the new additive is foreseen, should be involved in this procedure, as they have the technological expertise (see also section 1.2).

This section does foresee only the addition of additives, but does not take into consideration the removal of additives. Should there not also be a paragraph for this case?