codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 (a) **CX/FAC 06/38/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-eighth Session

The Hague, the Netherlands, 24 – 28 April 2006

DRAFT REVISION OF THE PREAMBLE OF THE GSFA

Comments at Step 6 in response to CL 2005/36-FAC by Canada, Mexico, Morocco, United States, ELC and IFU

CANADA

Canada participated in the Working Group led by China on the General Principles of the General Standard for Food Additives. This Working Group prepared a separate document submitted for comments (CX/FAC 06/38/7 of December 2005, Agenda Item 6(a)). We suggest that the diagram "Proposed Procedure for Consideration of the Entry and Review of Food Additives in the GSFA" (last page) of Appendix VII, ALINORM 05/28/12 be replaced by the Proposed Diagram as presented in the Report of the Working Group, CX/FAC 06/38/7.

MEXICO

- It is recommended that the translation into Spanish of "*level"* be either « nivel » or «concentración » and not « dosis », for being technically clearer.
- In numeral 2C, the permitted previous concentration should be replaced by concentration of origin or naturally occurring concentration.
- Annexe A, Contains guidelines for determining the maximum levels of the additives to which the JECFA has assigned a numeric Recommended Daily Intake.

MOROCCO

During the 37th CCFAC, a large discussion took place about the GSFA preamble. Either in the physical working group or in the plenary, Morocco argued about the section 3.2 of the preamble, and specifically about its wording.

Because this section is at the center of the risk management process to include or not to include a food additive in the GSFA, Morocco tries to make sure that all future users of the preamble are clear on the meanings. It tries also to propose a wording that is up to date and takes into account the widespread modernization that took place in the last 10 years

The section 3.2 was first written more than ***30 years ago***, and is older than some of our delegates. It includes a wording that might collide today with new terminology

Furthermore, the codex system is supposed to build standards for the many years ahead and not change them too many times.

The ***modernization*** process in terminology is taking place today everywhere in the world. For instance, the European commission, with its hygiene package; the USFDA or the USDA, are in the course of reshuffling some of their regulations by using new wording.

The words used in section 3.2 are perfectly understandable in plain English, and today's people understand their meaning.

However, these same words are going to become less and less acceptable and more and more difficult to understand for future users, which is going to create misinterpretations in the application of the GSFA, and possible conflicts in international trade.

The main problem in that section 3.2 comes from the use (or rather the misuse) of the word "quality".

According to several dictionaries, the word quality has quite a few meanings:

- an essential and distinguishing attribute of something or someone;
- a degree or grade of excellence or worth;
- a characteristic property that defines the apparent individual nature of something;
- choice: of superior grade; "choice wines"; "quality paper"; "select peaches"
- of high social status; "people of quality"; "a quality family"

It is also used in expressions like:

- hygienic quality
- sensorial quality
- technological quality
- keeping quality
- nutritional quality
- microbiological quality
- physical quality
- chemical quality
- …….

Some synonyms are also used like:

- nutritional properties
- nutritional value
- nutritional parameters
- nutritional needs
- nutritional characteristics
- nutritional composition
- nutritional content
- nutritional status
- nutritional requirements
- ……..

When used in so many ways a word does not mean anything, and becomes a source of confusion. That is the reason why the ISO (International Standards Organization) has put forward a definition of the word "quality" in its standard ISO 9001 version 2000: Quality Management Systems – Fundamentals and Vocabulary.

It states the following:

- <u>QUALITY:</u> degree to which a set of **inherent characteristics** fulfils **requirements**

The term “quality” can be used with adjectives such as poor, good or excellent. **“Inherent”,** as opposed to “assigned”, means existing in something, especially as a permanent characteristic

- Characteristic: distinguishing feature

A characteristic can be inherent or assigned. A characteristic can be qualitative or quantitative.

There are various classes of characteristic, such as the following:

- Physical (e.g. mechanical, electrical, chemical or biological characteristics);
- Sensory (e.g. related to smell, touch, taste, sight, hearing);
- Behavioral (e.g. courtesy, honesty, veracity);
- Temporal (e.g. punctuality, reliability, availability);
- Ergonomic (e.g. physiological characteristic, or related to human safety);
- Functional (e.g. maximum speed of an aircraft).

- Requirement: need or expectation that is stated, generally implied or obligatory

So, and according to this internationally recognized standard, the use of an adjective with the word **quality** is restricted to certain types, while the word **characteristic** can accept all sorts of adjectives.

This seems also to be the approach taken by the USFDA trough the definition given to a food additive (21 CFR chap.1, subchapter b— part 170—food additives, subpart a—general provisions § 170.3 definitions) where the word **characteristic**, present four times, is preferred.

This definition states the following:

“(e)(1) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the **characteristics** of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the **characteristics**, directly or indirectly, of food packed in the container. ‘‘Affecting the **characteristics** of food’’ does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other **characteristic** in the food, may be a food additive.

In the European Union as well,the word characteristic is used when it comes to foodstuffs, while the word quality is used when it comes to diets. That is what is published in a Bulletin EU 12-2000/Health and consumer protection (4/20) :

“*1.4.71.* Council resolution on health and nutrition (*Adopted on 14 December*)

The Council expressed concern about the consequences of an unbalanced diet and noted that information on the nutritional **characteristics *of foodstuffs*** and on the nutritional **quality *of diets*** is not sufficiently guaranteed. It therefore invited the Commission - in its action plan on nutrition and recommendations for dietary guidelines - to study ways of promoting better nutrition within the European Union as a determining factor for health”

For all these reasons and others, we are proposing to replace, in the section 3.2,the word **quality** by the word **characteristic** (or to a lesser extent by the word **requirement**).

As for the phrase ”keeping quality”, the replacement could be done either by the phrase “ keeping characteristic “, or change it all together by a more modern expression like “shelf life”.

As a conclusion, we propose the following wording for the section 3.2:

> “”a) to preserve the nutritional characteristics of the food; an intentional reduction in the nutritional characteristics 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 characteristics (or shelf life) or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;

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

UNITED STATES

This responds to CL 2005/36-FAC (July 2005) which requests comments at Step 6 on the *Draft revised Preamble of the GSFA* (Codex General Standard for Food Additives) presented in Appendix VII of ALINORM 05/28/12, the Report from the 37th session of the Codex Committee on Food Additives and Contaminants (CCFAC). The United States of America appreciates the opportunity to provide the following comments for consideration at the 38th CCFAC. Our comments are presented in the attached Annex.

ANNEX

United States Comments on the Draft revised **Preamble** of the GSFA (ALINORM 05/28/12, Appendix VII)

Footnote 2 – We recommend a revision to read: "...pose a safety concern under conditions of use described by JECFA as being of no toxicological concern (e.g., use levels under defined circumstances)."

Section 1.2, last sentence – We propose inserting '**the**" in front of "Codex", to read "....the Codex Committee..."

Section 1.4, first paragraph – We propose inserting "**numeric**" in front of "food additives", to read "...establishing numeric maximum levels...".

Footnote 6, 2nd sentence - It is not correct to refer to a JECFA recommendation of an "acceptable level of treatment" as an ADI. Therefore, we propose revising the sentence to: "The phrase 'acceptable ADI' refers to an evaluation by JECFA which established safety on the basis of an acceptable level of treatment of a food, limited numerically or by GMP, rather than on a toxicologically established ADI (see Summary of Evaluations....)."

Section 4, 2nd paragraph – We recommend that the paragraph "The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Standard;" should be designated as paragraph a) and indented. The existing paragraphs a) and b) should be redesignated as b) and c), respectively.

Section 4.2, 1st paragraph – We recommend that after "unacceptable", delete "in" and insert "for foods belonging to". Thus, "...ingredient is unacceptable for foods belonging to the following food categories...".

Footnote 10 , 1st sentence – We recommend deleting "- 2001". By not citing the year of adoption, the version to be consulted should always be the most recent.

Footnote 10, Sentences 2-4 – We believe that these sentences need revision because of the impending publication of JECFA's updated compendium of specifications. Proposed new language is:

"Codex specifications are those prepared by JECFA, which have been adopted by the Commission. All JECFA specifications are published in the FAO 'Combined Compendium of Food Additive Specifications,' which consists of four volumes published in 2006. The specifications are also available at the JECFA website (http://www.fao.org/es/esn/jecfa/database/cover.htm). Although specifications for flavouring agents are not included in the printed compendium, excepting those few having an additional technological function as a food additive (e.g., preservatives), they are included in the online searchable database at the JECFA website."

Although the GSFA does not contain provisions for flavouring agents, we believe this last sentence is informative, as CAC/MISC 6 also contains references to Codex-adopted specifications for flavouring agents.

Section 7.2, 1st paragraph – We recommend changing "after" to "**on the basis o**f". Thus, "...revised by the CCFAC on the basis of requests...".

Section 7.2, 5th bullet – We propose insertion of a new sub-bullet: "For additives with an acceptable ADI, either a numerical level for the acceptable level of treatment of a food or a level of GMP, consistent with the JECFA evaluation."

Section 7.2, 5th bullet, 1st sub-bullet – In some cases, a use level of GMP may be appropriate for an additive assigned a numerical ADI. We propose revising the sub-bullet to read: "For additives with a numerical ADI, a numerical maximum level for each specified use, although for certain cases, a level of GMP may be appropriate;"

ELC

ELC, the Federation of European Food Additives, Food Enzymes and Food Cultures Industries, welcomes that the above-mentioned document is submitted for comments at step 6 of the Procedure.

ELC would like to point out that numerical limits should not necessarily be set for additives with numerical ADIs. The CCFAC, in the report of its 35th session (ALINORM 03/12A, April 2003, article 44) actually acknowledged that exceptions can be made from the principle that all additives assigned a numerical ADI should be assigned maximum use levels. The possibility of use according to GMP of additives with numerical ADIs should be maintained under certain circumstances: in particular, ELC regrets that **the draft document does not mention clearly the possibility of use according to Good Manufacturing Practice of additives with numerical ADIs that are unlikely to be exceeded, e.g. additives with high numerical ADIs; or additives used in table-top sweeteners (food category 11.6).**

We understood from the discussion in the working group at the 2005 CCFAC session that it would not be appropriate to include such statement under Paragraph 3.3 of the draft revised preamble. We believe that reference to this principle could nevertheless be made:

- either under paragraph 7.2 "Revision" – 5th bullet point – 1st sub-bullet point that would read:

  " *For additives with a numerical ADI, a numerical maximum level for each specified use.* ***Under certain circumstances, and in particular for additives with numerical ADIs that are unlikely to be exceeded, the maximum level can refer to GMP***".

  Alternatively, the statement could be provided as a footnote to this sub-bullet point.

- or as a footnote to the text box "discussion on conditions of use in Specific Food Categories" of the Diagram. It should be considered that the previous draft diagram (CX/FAC 05/37/7 –Appendix II) included the following footnote: "*entries in GSFA Table 1 and 2 for additives with a numerical ADI are normally defined by numerical maximum levels, however, CCFAC may choose GMP where this is appropriate*", which was omitted in the new proposed diagram.

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.

We would like to propose the following amendments (in italic writing):

1.2 Foods in Which Additives May Be Used

This Standard sets forth the conditions under which food additives may be used in all foods, whether or not they have previously been standardized by Codex.

1.2.1 Role of the Commodity Committee

Codex commodity committees, taking into account the conditions of use of this standard, have the responsibility and expertise to appraise and justify the technological need for the use of additives as well as their necessary use levels in foods subject to a commodity standard. The food additive provisions of Codex commodity standards shall be included in this Standard and adopted by the Codex Committee on Food Additives and Contaminants.

1.2.2 Role of the Codex Committee on Food Additives and Contaminants

The Codex Committee on Food Additives and Contaminants has the responsibility and expertise of all health aspects regarding the use of additives. This includes the safety of the additives as well as their tolerable use level. The information given by the commodity committees may also be taken into account by the Codex Committee on Food Additives and Contaminants when considering food additive provisions in similar non-standardized foods. When a food is not covered by a commodity committee, the Codex Committee on Food Additives and Contaminants will appraise the technological need.

Reason for the proposed amendment:

The existing text does not fix the competences and responsibilities of the commodity committee on one side and CCFAC on the other side. 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.

5. Food Category System

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. *If this rule leads to inconsistency with the commodity standard, the commodity committee may request CCFAC to apply this exception to the respective food category.*

7.2 Revision

The food additive provisions of this Standard may be revised by CCFAC after requests submitted by Codex Committees, Codex members, or the Codex Alimentarius Commission. Information to support amendment of this Standard shall be provided by the proposing body. Supporting information provided to the CCFAC should include, as appropriate:

Revoke of an additive:

- *All arguments for the revoke of an additive*

Addition of an additive:

- Specifications for the food additive;
- A summary of the JECFA safety evaluation of the food additive;
-

Reason for the proposed amendment:

This section does foresee only the addition of additives, but does not take into consideration the removal of additives. Therefore we propose the addition of a separate paragraph to revoke an additive.

The diagram:

Proposed Procedure for Consideration of the Entry and Review of Food Additives in the GSFA

has been replaced by the latest version established by the Working Group on the General Principles of the Codex General Standard for Food Additives (see Annex), however with the amendment, that from the box.

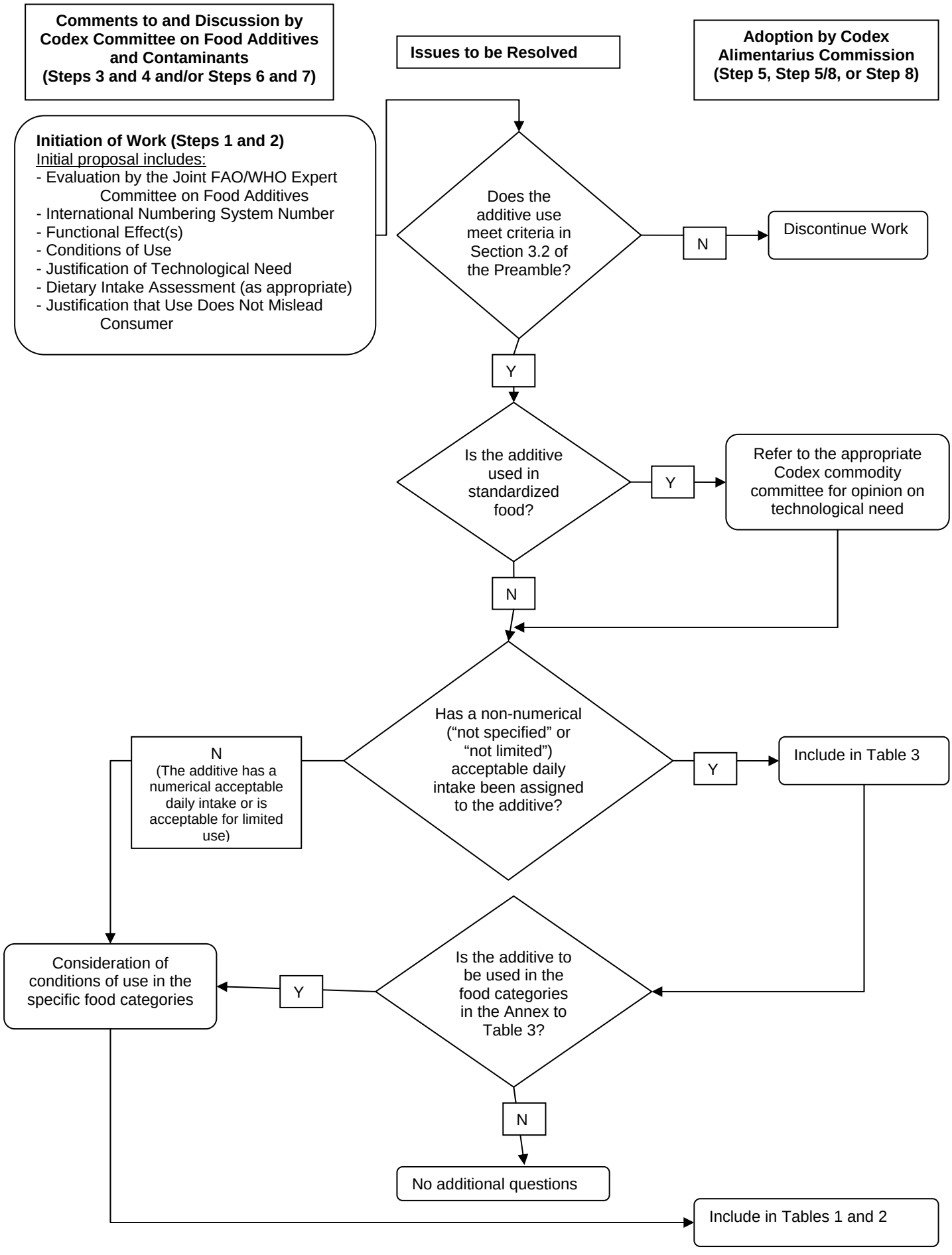
Refer to the appropriate Codex commodity committee for opinion on technological need

a line with **No for this Food Category** has to be added to the box

Discontinue Work

Reason for the proposed amendment:

As the commodity committee has the expertise to decide on the technological justification of a new additive (see also 1.2), it must be in the competence of this committee to say No to a new additive for the use in the respective food category.


Comments to and Discussion by Codex Committee on Food Additives and Contaminants (Steps 3 and 4 and/or Steps 6 and 7)
Issues to be Resolved
Adoption by Codex Alimentarius Commission (Step 5, Step 5/8, or Step 8)
Initiation of Work (Steps 1 and 2)
Initial proposal includes:
- Evaluation by the Joint FAO/WHO Expert Committee on Food Additives
- International Numbering System Number
- Functional Effect(s)
- Conditions of Use
- Justification of Technological Need
- Dietary Intake Assessment (as appropriate)
- Justification that Use Does Not Mislead Consumer
Does the additive use meet criteria in Section 3.2 of the Preamble?
N
Discontinue Work
Y
Is the additive used in standardized food?
Y
Refer to the appropriate Codex commodity committee for opinion on technological need
N
Has a non-numerical ("not specified" or "not limited") acceptable daily intake been assigned to the additive?
Y
Include in Table 3
N
(The additive has a numerical acceptable daily intake or is acceptable for limited use)
Is the additive to be used in the food categories in the Annex to Table 3?
Y
Consideration of conditions of use in the specific food categories
N
No additional questions
Include in Tables 1 and 2