

## WORKING PRACTICES FOR THE INCORPORATION AND ENDORSEMENT OF FOOD ADDITIVE PROVISIONS FOR COMMODITY AND REGIONAL COMMITTEES

### 1. Scope

These working practices<sup>1</sup> apply to the development of food additive provisions relating to newly initiated or amended commodity standard(s)<sup>2</sup>, for food additives that are already listed in the GSFA<sup>3</sup>.

### 2. Introduction

The aims of these working practices are to ensure that the GSFA is strengthened as the single reference in Codex for food additives and ensure that there is no further divergence of food additive provisions in the GSFA with commodity standards. This process is referred to as incorporation and endorsement, as defined in section 3.

In developing commodity standards, Commodity/Regional Committees should first examine the relevant GSFA food additive provisions with a view to deciding whether they are suitable for their needs, or whether further amendments to the GSFA are required so that a general reference to the GSFA could be included in the commodity standard(s) as the incorporation of specific food additive provisions in commodity standards should be exceptional and minimised as much as possible.

### 3. Definitions

For the purpose of this standalone working practices document, the following terms are defined:

*“Incorporation”* - the inclusion of food additive provisions in the GSFA resulting from the initiation of new and/or amended commodity standards.

*“Endorsement”* - the process whereby CCFA approves the food additive section contained in commodity standards in accordance with the Procedural Manual.

### 4. Principles

- (i) That the GSFA be strengthened as the single reference in Codex for food additives.
- (ii) That no further divergence of food additive provisions in the GSFA with commodity standards are created, such that the work on alignment<sup>4</sup> can be completed.
- (iii) That a general reference to the GSFA is the optimal approach, while the incorporation of *specific* food additive provisions in commodity standards should be minimised as much as possible.
- (iv) That all food additive provisions in the commodity standards require endorsement by CCFA, consistent with the Procedural Manual, before their adoption by CAC.
- (v) That the GSFA is amended at the same CCFA meeting as the endorsement of food additive provisions in commodity standards, and these are both adopted concurrently by the CAC.
- (vi) That CCFA engage collaboratively with the Commodity/Regional Committees on food additive provisions to ensure timely and appropriate outcomes.

### 5. Key considerations for the development of the Commodity Standard(s) and the amendment of the GSFA

#### 5.1 Collaboration between Committees and Commodity/GSFA experts

It is highly desirable that experts (i.e. expert(s) on the commodity and expert(s) on the GSFA) are involved to facilitate the timely development of the food additive section in Commodity Standard(s) and the amendment to the GSFA. This will minimise the iterative exchange between the Committees that may be required before agreement is reached.

The GSFA and commodity experts should facilitate the information exchange between Committees (Commodity/Regional Committee or CCFA) at an early stage in the process which would enhance the efficiency of the work and will thus minimise the back-and-forth dialogue between the Committees.

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<sup>1</sup> These working practices should be used for all new and proposed changes to food additive provisions irrespective of whether the commodity standard has been aligned with the GSFA. It is distinct from the work on alignment of adopted food additive provisions for which the existing CCFA alignment procedure would continue to be used.

<sup>2</sup> Commodity standards can be developed either by Commodity Committees or FAO/WHO Coordinating Committees (i.e. Regional Committees).

<sup>3</sup> Food additives that are listed in the GSFA for any food categories in Tables 1, 2 or 3.

<sup>4</sup> Alignment is the retroactive process by which the adopted food additive provisions in previously developed commodity standards are aligned with those of the GSFA.

## 5.2 Incorporation of a general reference in commodity standards

In developing the commodity standard, a general reference to the GSFA should be suitable in most cases, with the relevant provision in the GSFA being amended by the use of Notes, as appropriate. The commodity standard may also list the functional classes to provide further information on the intended uses. In complex situations, a functional class table may be required. When referring to the GSFA, a specific list of food additives should not be included in commodity standards but be reflected in appropriate amendments to the GSFA.

Where a general reference to the GSFA is included in the commodity standard(s), the Commodity/Regional Committees should review all the existing food additive provisions in the GSFA relating to food(s)/product(s) included in the commodity standard, to ensure their suitability.

An example of a general reference to the GSFA is as follows:

“[Food additive functional class] used in accordance with Tables 1 and 2 of the General Standard of Food Additives in food category x.x.x.x [FC name] or listed in Table 3 of the GSFA are acceptable for use in foods conforming to this standard.”<sup>5</sup>

In situations where **no** food additives are allowed in a particular commodity standard, this should be clearly stated in the commodity standard(s). Examples of an appropriate sentence that should be included in the commodity standard(s) are: “No food additives are permitted in [foods/products] conforming to this standard”, or “No food additives are permitted in [specific name of food]”. An appropriate amendment to the GSFA is still required to reflect this.

## 5.3 Identification of Food Categories

It is important to identify the GSFA food category(s) in which the commodity(s) belong, while noting that the GSFA Food Category system should be used as a default. In some cases, there is a one-to-one relationship between the commodity standard and the GSFA. However, the description of commodities in the commodity standard does not always correspond to a GSFA food category(s).

In considering amendments to the GSFA, this difference in the scope of the commodities covered by the standards should be addressed by the use of exclusion notes (XS notes) to ensure the scope of the food additive provisions are not broader than required.

Where necessary, revisions to the existing food category(s) to accommodate specific foods may be appropriate with careful consideration. There are two situations relating to changes to the GSFA food category(s): (i) revisions to the current food category descriptors<sup>6</sup>; and (ii) a revision to the food category(s). Revisions to the food category(s) (ii above) includes both new and revised food categories and this change should be primarily considered by CCFA.

## 5.4 Consideration of functional classes, group food additives, use levels and further restrictions

For food additives that have multiple functional classes, these may be considered without restrictions to their functional classes. Alternatively, restrictions may be considered necessary, e.g. emulsifiers not being used as thickeners or stabilisers where appropriate.

Where restrictions are proposed, the Commodity/Regional Committees should be clear on the particulars regarding the scope of food additive use (i.e. the need to limit to very specific technical functions, whether all additives of a technical function can be used or only certain additives), and provide a justification on the restriction(s). The commodity standard(s) may include information on the functional classes. For most Commodity Standards this can be a simple list. However, for complex standards that capture a wide variety of foods or processes a functional class table may serve as a helpful reference to help the reader clarify what types of food additives may be used. In addition, a list of the applicable GSFA food categories may be helpful.

In considering food additives that share a numerical ADI, a justification should be provided where restrictions on the use of individual additives are proposed. The Commodity/Regional Committee should consider whether there is an existing use level in Table 1 and 2. Where necessary an alternative use level may be proposed where technologically justified.

The Commodity/Regional Committee should also determine if there are other factors that would cause certain food additives to be inappropriate.

## 5.5 The amendment of the GSFA

The approach to incorporation should be broadly consistent to that taken for new and revised amendments procedure to the GSFA, using the *Guidelines for the inclusion of specific provisions in Codex standards and*

<sup>5</sup> Procedural Manual, 31<sup>st</sup> edition. SECTION 2 ELABORATION OF CODEX STANDARDS AND RELATED TEXTS. Paragraph 91.

<sup>6</sup> CODEX STAN 192-1995 GSFA, Annex B, PART II: Food Category Descriptors.

*related texts*<sup>7</sup> of the Procedural Manual. This is especially the case for the safety aspects which need to be fully considered because in contrast to Alignment, which is a retrospective exercise, incorporation is for amended and new provisions for which the safety aspects may have not been previously considered. In addition, if the Regional Committee does not have the appropriate technical expertise, consideration of technological justification should be performed by CCFA at the request of the Regional Committee.

## **6. Preparation of proposals for additions or amendments of GSFA provisions and endorsement by CCFA**

Two alternative routes are available for the amendment of the GSFA relating to commodity standards, as outlined below. In choosing the route, the Commodity/Regional Committee should take account of the GSFA expertise available to them.

The Codex Secretariat to the Commodity/Regional Committees should ensure that the ToR of WGs considering the food additive provisions makes reference to this working practice document. The EWG report should include the template<sup>8</sup> (Annex 1) and state the route that has been used.

A decision tree outlining the recommended approach to the amendment to the GSFA to reflect new and amended food additive provisions, together with other explanatory information is at Annex 2.

### **6.1 Process where the Commodity/Regional Committee prepares a proposal for GSFA provisions relating to commodity standards (Route 1)**

The development of amendments to the GSFA would be undertaken primarily by the Commodity/Regional Committee with the initial draft commodity standard and the proposed amendments to the GSFA being submitted to the CCFA for consideration and endorsement.

The Commodity/Regional Committee should decide upon the food additives that are required for use in the Commodity at an early stage in the development of the Commodity Standard(s). Once this decision has been made, they should submit the information required for the endorsement by CCFA of the proposed food additive provisions. This information should include the completed template at Annex 1, the proposed amendments to the GSFA, the draft Commodity Standard(s), and where relevant the report of the EWG that considered the food additive provisions.

In order to ensure that expertise in the GSFA is available, the Chair of the Commodity Standard WG of the Commodity/Regional Committee should seek GSFA experts from the member countries participating in the development of the Commodity Standard. An alternative approach would be for the Chair to identify other GSFA experts, subject to their availability, to assist in the amendment of the GSFA. The Codex Secretariat should also assist with connecting GSFA and Commodity experts. The experts would work together to draft the food additive provisions, including the appropriate GSFA food category and notes, thereby facilitating efficiency and reducing the time frame for the development of the pertinent provisions in the GSFA.

The Commodity Standard WG would develop the completed templates at Annex 1 and include the general reference to the GSFA in the Commodity Standard(s), in collaboration with the GSFA expert(s). Once this work has been agreed by the Commodity/Regional Committee, the amendments to the GSFA and the Commodity Standard should be referred to CCFA for consideration and endorsement, with the assistance of the Codex Secretariat, consistent with section 2, para 58-63 of the PM<sup>9</sup>.

CCFA would review the amendments to the GSFA, including safety aspects of the proposed food additive provisions, and the other considerations listed in the *Guidelines for the inclusion of specific provisions in Codex standards and related texts*<sup>7</sup>. CCFA would endorse the proposed uses or provide suggestions to the Commodity/Regional committee, as appropriate.

If CCFA were to agree to all aspects, then the food additive section of the Commodity standards would be endorsed and both the commodity standards and the amendment to the GSFA would be advanced for adoption by CAC once the Commodity/Regional Committee has completed their work in developing the Commodity standard. Where CCFA has suggestions, then the Commodity/Regional Committee would respond to the information referred from CCFA, and present revised provisions to the next session of CCFA for subsequent endorsement.

In summary, the Commodity/Regional Committee would have primary responsibility for the development of the GSFA food additive provision(s) relevant to the specific commodities, noting that CCFA has to endorse the

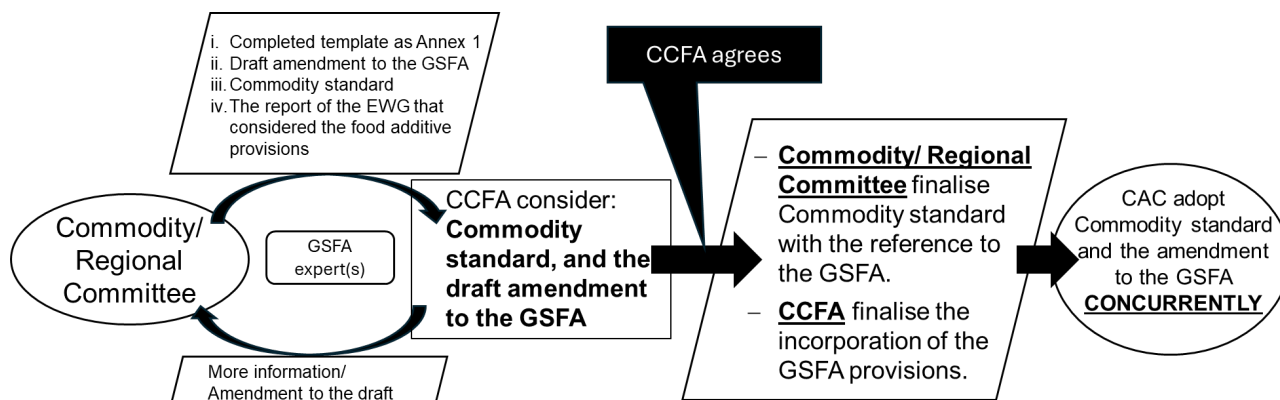
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<sup>7</sup> Procedural Manual, 31<sup>st</sup> edition. SECTION 2 ELABORATION OF CODEX STANDARDS AND RELATED TEXTS. Paragraphs 108-127.

<sup>8</sup> The information required in the template should be consistent with requirements in para 111-114 of the Procedural Manual, 31<sup>st</sup> edition.

<sup>9</sup> Procedural Manual, 31<sup>st</sup> edition. SECTION 2 ELABORATION OF CODEX STANDARDS AND RELATED TEXTS. Paragraphs 58-63.

provisions. Whereas the Commodity/Regional Committee are more familiar with the Commodity under consideration, a comprehensive technical understanding of the GSFA is required that would be provided by collaboration with a GSFA expert(s). The involvement of GSFA experts would reduce the risk of having to proceed through iterations (back-and-forth between the Commodity/Regional Committees and CCFA) that may result in delaying the development of Codex standards.



If route 1 is chosen and it subsequently becomes clear that the technical complexity requires further CCFA involvement, then a change to route 2 is possible.

## 6.2 Process where the Commodity/Regional Committee requests the CCFA to develop a proposal for GSFA provisions relating to commodity standards (Route 2)

The development of amendments to the GSFA would be undertaken primarily by CCFA based on a request and the submission of all relevant information by the Commodity/Regional Committees.

The Commodity/Regional Committee should decide the food additives that are required for use in the Commodity at an early stage in the development of the Commodity Standard(s). Once this decision has been made, they should submit the information required by CCFA. This information should include the completed template at Annex 1, the draft Commodity Standard(s), and where relevant the report of the WG that considered the food additive provisions.

The information would then be used by a CCFA WG to consider safety and to draft the necessary food additive provisions in the GSFA. This drafting work would be undertaken with a general mandate being agreed each year by CCFA (e.g. terms of reference of the WG). This general mandate would task the WG to consider all the requests provided by the Commodity/Regional Committee and proceed to develop the proposed amendments to the GSFA.

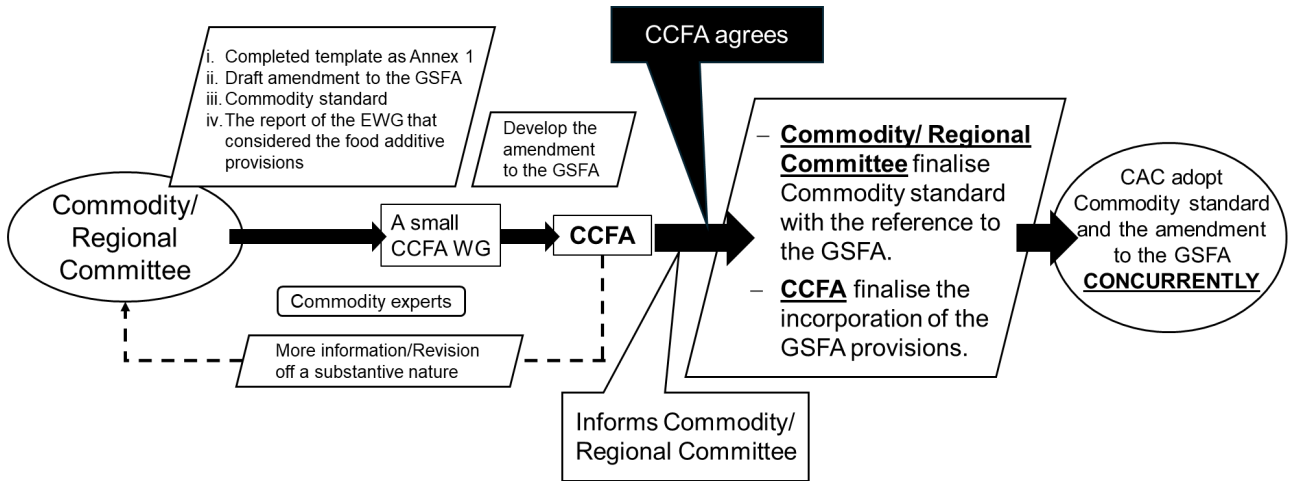
The WG should fully reflect the request(s) from the Commodity/Regional Committee but at the same time consider the safety of the proposed food additive provisions. Where needed, there would be collaboration between GSFA experts and Commodity expert(s) in order to minimize the iterative exchange between the Committees, and ensure the amendments to the GSFA appropriately reflect the request received. This collaboration could be done by hosting a joint virtual WG meeting involving experts from both CCFA and Commodity/Regional Committees.

The drafted provisions would then be presented to CCFA for agreement. In cases where further information, or clarification, is required from the Commodity/Regional Committee, this would be requested by CCFA before the food additive provisions in the commodity standard are endorsed.

Once CCFA agrees, the Commodity/Regional Committee will be informed of the amendments to the GSFA, although formal agreement by the Commodity/Regional Committee would not be required when the amendments of the GSFA reflects the request received from the Commodity/Regional committee. However, where the changes proposed by CCFA food additive provisions are of a substantive nature, these would be referred back to the Commodity/Regional Committee for their further consideration.<sup>10</sup>

In summary, CCFA would have primary responsibility for the development of the food additive provision(s) based on a request and information provided by a Commodity/Regional Committee. This option has the advantage that CCFA has the comprehensive technical understanding of the GSFA that may not be available to the Commodity/Regional Committees. This option would follow the procedures described in the *Guidelines for the inclusion of specific provisions in Codex standards and related texts*<sup>7</sup>. The flowchart for Route 2 is provided below.

<sup>10</sup> Procedural Manual, 31<sup>st</sup> edition. SECTION 2 ELABORATION OF CODEX STANDARDS AND RELATED TEXTS. Paragraph 58.



**Annex 1****TEMPLATES FOR THE SUBMISSION OF PROPOSALS FOR NEW AND/OR REVISIONS OF FOOD ADDITIVE PROVISIONS IN THE GSFA RELATING TO COMMODITY STANDARDS**Introduction

Two templates are provided for the submission of proposals for new and/or revisions of food additive provisions in the GSFA relating to Commodity Standards. Template 1 is for Route 1, Template 2 is for Route 2.

In completing these templates, it is not necessary to include information that is already clearly included in the WG report that is associated with the development of the commodity standard.

A separate table should be completed for each food additive, or a group of food additives.

Template 1 – (Route 1)

This template outlines supporting information that should be provided to CCFA to support amendment of the GSFA where the Commodity/Regional Committee decide to prepare the first draft. The template includes the format that should be used by the Commodity/Regional Committee in the preparation of amendments to the GSFA.

The template includes Table 2 provisions, but not Table 1 provisions. This is because when Table 2 provisions are adopted, this will result in consequential changes to Table 1.

Where the commodity standard(s) makes a general reference to the GSFA and there are no changes to the maximum use levels of the GSFA, it is not necessary to complete Template 1.

Template 2 – (Route 2)

This template outlines supporting information that should be provided to the CCFA to support amendment of the GSFA, where the Commodity/Regional Committee request the CCFA to prepare these GSFA amendments.

**Template 1 – Information required<sup>11</sup> for route 1**

## Part A: Basic information

<b>THE PROPOSAL IS SUBMITTED BY:</b>	<i>Include the Committee that submits the proposal</i>
<b>NAME OF THE COMMODITY/REGIONAL STANDARD:</b>	<i>Include the name of the standard</i>
<b>IDENTITY OF THE FOOD ADDITIVE:</b>	
<b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>  For certain additive(s) belonging to a group food additive, include justification(s) where restrictions are proposed.	<i>Include the name of the additive or the group of the additives</i>
<b>INS Number</b>	<i>Include the INS number</i>
<b>Functional Class</b> <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>  Include justification(s) where restrictions are proposed.	<i>Include the name of the functional class(es) performing the intended technological effect.</i>  <i>When relevant, explain why some additional functional classes associated with the additive are not appropriate (i.e. explain, whether and why there should be a restriction for certain function class(es) associated with the additive)</i>
<b>EVALUATION BY JECFA:</b>	
<b>Evaluation by JECFA</b> <i>Reference to the JECFA evaluation (including year and JECFA session; full ADI (numerical or “not specified”); specifications monograph).</i>	<i>Include the reference to the JECFA evaluation and a summary of the outcomes and their relevance for the proposal.</i>
<b>JUSTIFICATION:</b>	
<b>Justification for use and technological need</b>  <i>Supporting justification based on the criteria in Section 3.2 &amp; 3.3(a) of the Preamble of the General Standard for Food Additives.</i>	<i>Indicate whether the use is proposed broadly across all foods covered by the standard or only for some specific products.</i>  <i>Include information relating to the use, and the use level, of the additive based on 3.3(a) and the objectives in Section 3.2 of the Preamble of the GSFA.</i>
<b>Justification that the use does not mislead consumer</b>  <i>Assessing whether the use of this additive in the intended food(s) modify any characteristic of the food that might mislead the consumer.</i>	<i>Include information justifying that the proposed use does not misled consumer, e.g. as regards changing the nature, substance, quality or nutritional quality of the food, the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques by which the consumer might be misled.</i>
<b>Correspondence between commodity/regional standard and food category(s)</b>	<i>Provide an explanation as to how the food category(s) corresponds to the commodity/regional standard, for complex situations.</i>  <i>Where there is no appropriate corresponding food category(s), revisions to the existing food category(s) may be necessary in order to accommodate specific foods. While revisions to the current food category(s) <u>descriptors</u> may be proposed by the Regional/Commodity Committee,</i>

<sup>11</sup> It is not necessary to include information that is already clearly included in the WG report that is associated with the development of the commodity standard. Similarly, it is not necessary to duplicate information in Part A of Template 1, if the information is unambiguously provided in Part B of Template 1. However, a reference to the relevant part of the WG report or Part B of Template 1 should be included e.g. “this information is already included in the WG report”.

	<i>changes to a food category(s) (new and revised food category(s)), should be primarily considered by the CCFA. A full explanation should be provided (if not already in the WG report).</i>
<b>Safe use of additive: Dietary intake assessment (as appropriate)</b>  The safety of the proposed use of the food additives should be fully considered, taking into account dietary intake from all food sources and where relevant the intake by special groups of consumers.	Table 3 additive:  <input type="checkbox"/> Yes  <input type="checkbox"/> No. <i>Please provide information on the dietary intake. Indicate whether the proposed use is included in the existing JECFA assessment and what the outcome of the assessment is. Alternatively, use the intake assessment of Codex member(s) or the procedure of Annex A of the GSFA.</i>

### Part B: Format for the proposed amendments<sup>(1)</sup> to the GSFA

PROPOSED AMENDMENTS TO TABLE 2 AND 3 OF THE GSFA RELATING TO [INSERT NAME OF COMMODITY COMMITTEE]

#### 1. PROPOSED AMENDMENTS TO TABLE 2 OF THE GSFA (food category numerical order)

##### 1.1 PROPOSED AMENDMENTS TO FOOD CATEGORY [INSERT FOOD CATEGORY NUMBER]

Food Category No. <sup>(2)</sup>		[INSERT FOOD CATEGORY]		
Additive	INS	Step/Year adopted (where applicable)	Max Level <sup>(3)</sup> <sup>(4)</sup> (mg/kg)	Notes <sup>(5)</sup>

#### 2. PROPOSED AMENDMENTS TO TABLE 3 OF THE GSFA

##### 2.1 AMENDMENTS TO TABLE 3

INS	Additive	Functional Class	Year adopted (where relevant)	Specific allowances

##### 2.2 AMENDMENTS TO REFERENCE TO COMMODITY STANDARDS FOR GSFA TABLE 3 ADDITIVES.

[INSERT FOOD CATEGORY NUMBER]	[INSERT FOOD CATEGORY]

Explanatory notes:

- <sup>(1)</sup> For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strike through~~ text, and changes or additions noted in **bold font**.
- <sup>(2)</sup> Food category number and name, as listed in Annex B of the GSFA.
- <sup>(3)</sup> For consistency, the maximum use level should be expressed on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g. "not-specified").
- <sup>(4)</sup> Use levels that differ than those already in the GSFA should be based on that necessary to achieve the desired technological effect.
- <sup>(5)</sup> Specific restrictions on the use of the food additive to be included as Notes (e.g. limitation of use to specific products in a food category). Examples of potentially relevant notes are be found in the GSFA.

**Template 2 – Information required<sup>12</sup> for route 2**

<b>THE PROPOSAL IS SUBMITTED BY:</b>	<i>Include the Committee that submits the proposal</i>		
<b>NAME OF THE COMMODITY/REGIONAL STANDARD:</b>	<i>Include the name of the standard</i>		
<b>IDENTITY OF THE FOOD ADDITIVE:</b>			
<b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>  For certain additive(s) belonging to a group food additive, include justification(s) where restrictions are proposed.	<i>Include the name of the additive or the group of the additives</i>		
<b>INS Number</b>	<i>Include the INS number</i>		
<b>Functional Class</b> <i>As listed in Class Names and the International Numbering System for Food Additives (CXG 36-1989)</i>  Include justification(s) where restrictions are proposed.	<i>Include the name of the functional class(es) performing the intended technological effect.</i>  <i>When relevant, explain why some additional functional classes associated with the additive are not appropriate (i.e. explain, whether and why there should be a restriction for certain function class(es) associated with the additive)</i>		
<b>EVALUATION BY JECFA:</b>			
<b>Evaluation by JECFA</b> <i>Reference to the JECFA evaluation (including year and JECFA session; full ADI (numerical or “not specified”); specifications monograph).</i>	<i>Include the reference to the JECFA evaluation.</i>		
<b>JUSTIFICATION:</b>			
<b>Justification for use and technological need</b> <i>Supporting justification based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives.</i>	<i>Indicate whether the use is proposed broadly across all foods covered by the standard or only for some specific products.</i>  <i>Include information relating to the use, and the use level, of the additive based on 3.3(a) and the objectives in Section 3.2 of the Preamble of the GSFA.</i>		
<b>Justification that the use does not mislead consumer</b> <i>Assessing whether the use of this additive in the intended food(s) modify any characteristic of the food that might mislead the consumer.</i>	<i>Include information justifying that the proposed use does not misled consumer, e.g. as regards changing the nature, substance, quality or nutritional quality of the food, the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques by which the consumer might be misled.</i>		
<b>PROPOSED USE(S) OF THE FOOD ADDITIVE <sup>(1)</sup>:</b> <i>The rows below may be copied as many times as needed.</i>  Include consideration of relevant notes to reflect restrictions.	The proposal for:  <input type="checkbox"/> a new provision; or  <input type="checkbox"/> revising an existing provision in Tables 1 and 2 of the GSFA; or  <input type="checkbox"/> revising an existing provision in Table 3 of the GSFA		
<b>Food Category No. <sup>(2)</sup></b>	<b>Food Category Name <sup>(2)</sup></b>	<b>Maximum Use Level <sup>(3)(4)</sup> (mg/kg)</b>	<b>Comments <sup>(5)</sup></b>

<sup>12</sup> It is not necessary to include information that is already clearly included in the WG report that is associated with the development of the commodity standard. However, a reference to the relevant part of the WG report should be included e.g. “this information is already included in the WG report”.

- (1) For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~strikethrough~~ text, and changes or additions noted in **bold** font.
- (2) Food category number and name, as listed in Annex B of the GSFA.
- (3) For consistency, the maximum use level should be expressed on the same basis as the ADI.  
A numerical use level should be provided for a food additive assigned a numerical ADI.  
GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g. “not-specified”).
- (4) Use levels that differ than those already in the GSFA should be based on that necessary to achieve the desired technological effect.
- (5) Comments on specific restrictions on the use of the food additive to be included as Notes (e.g. limitation of use to specific products in a food category). Examples of potentially relevant notes are be found in the GSFA.

## Annex 2

**GUIDANCE TO THE COMMODITY/REGIONAL COMMITTEE AND DECISION TREE ON THE AMENDMENT(S) TO THE GSFA**

The development of food additive provisions should comply with the Preamble of the GSFA, especially the criteria on safety and technological justification contained in Section 3 - General principles for the use of food additives.

The amendments to the GSFA, resulting from Commodity Standard food additive provisions, need to address the requirements in all three Tables and make appropriate amendments to each as required.

This section explains the format of the GSFA (see Section 6 of the Preamble to the GSFA). The GSFA contains three tables that may need to be amended.

Table 1 (*Additives permitted for use under specified conditions in certain food categories or individual food items*) is an alphabetical list of food additives, including the International Numbering System (INS) number and functional class. Each food additive entry lists the individual food categories which have a provision for that food additive. The maximum use level, any notes linked to the provision, step, and year adopted are detailed for each provision.

Table 2 (*Food categories or individual food items in which food additives are permitted*) is a numerical list of food categories. Each food category entry lists the food additives that have provisions for the food category in alphabetical order. The INS number for the food additive, and the maximum use level, notes, step and year adopted are also listed. The information in Table 2 is the same as in Table 1, just in a different format.

Table 3 (*Additives permitted for use in food in general, unless otherwise specified, in accordance with GMP*) contains a list of food additives that may be used in food in general at GMP unless specifically excluded. The Annex to Table 3 provides a list of specific food categories or individual food items that are excluded from the general conditions of Table 3, in which case the provision is listed in Tables 1 and 2. Table 3 lists the food additives in alphabetical order, along with their INS number, the functional class, the year adopted and some specific Codex commodity standards to which it is acceptable.

The fifth column of Table 3 lists Table 3 food additives in relation to **specific** commodity standards. However, where the commodity standard covers the use of foods in food categories that are contained in the Annex to Table 3, then Table 3 does not apply to the commodity standard.

In relation to the relevant functional classes, the information in Table 3 in the third column 'Functional Classes' should be used, except where the reference is made to "certain" Table 3 additives or "certain" functional classes. In these latter cases, reference should be made to the fifth column of Table 3 to determine the scope of the food additive provisions.

Where commodity standards allow Table 3 food additives on a **general** basis or based on a **functional class**, **these standards are listed** in the table entitled "References to Commodity Standards for GSFA."

Questions to be addressed

Some general questions need to be asked for each of the food additive provisions listed in the Codex commodity standard before they can be added into the GSFA. These questions have been answered in the positive for food additive provisions listed in the GSFA. These questions are articulated further in Section 3 of the Preamble to the GSFA. They are also summarised in the Guidelines for inclusion of specific provisions in Codex standards and related texts: Procedures for consideration of the entry and review of food additive provisions in the General Standard for Food Additives of the Codex Alimentarius Commission Procedural Manual. In summary, the questions are:

- Has JECFA completed a safety evaluation (i.e., assigned a full acceptable daily intake (ADI)) or concluded the food additive is safe for the proposed purpose?
- Is there a JECFA specification for the food additive?
- Is the technological need/justification for use of the food additive accepted by the Codex Commodity Committee, and does it meet one or more of the need/justifications listed in section 3.2 (a)-(d) of the GSFA preamble?
- Does the food additive have an INS name, number and functional class listed in the Class Names and International Numbering System for Food Additives (CAC/GL 36-1989)?
- Is the functional class for use of the food additive for the food category in the GSFA agreed by the Commodity Committee?

- Is there a 1:1 relationship between an existing GSFA food category(s) and the Commodity Standard? A 1:1 relationship means that all foods that comply with a Codex commodity standard are the only foods that are included in the relevant GSFA food category. For example, for infant formula there is a direct correlation between FC 13.1.1 and CXS 72-1981.

Commodity Committees may need to address whether there is a 1:1 relationship between the Codex commodity standard and the GSFA food category, as they have the best understanding of the relevant Codex commodity standard and foods captured by the commodity standard.

However, most GSFA food categories do not have a 1:1 correspondence with a Codex commodity standard. Foods that comply with a Codex commodity standard are termed “standardized foods”. There may be other foods that are included in a GSFA food category that do not comply with a Codex commodity standard. These are termed “non-standardized foods”. Food categories that do not have a 1:1 relationship between the Codex commodity standard and the GSFA food category include both standardized food and non-standardized foods.

Information on the food category system of the GSFA is provided in Annex B of the GSFA, especially Part II (Food Category Descriptors). Annex C (*Cross-reference of Codex standardised foods with the food category system used for the elaboration of the GSFA*) of the GSFA provides a list of Codex commodity standards and the relevant GSFA food category number, so is a very valuable resource to assist with this work.

The type of relationship between a Codex commodity standard and a GSFA food category (1:1 correspondence or not) will determine how the incorporation is accomplished, especially whether specific notes are needed for the GSFA provisions to address non-standardized foods.

#### Summary of process to be undertaken

It is easiest to consider amendments to the food additive provisions in the GSFA by revising Table 2 of the GSFA. This is because Table 2 is organized by food categories which link directly to the Codex commodity standards. Once these Table 2 provisions are adopted, this will result in consequential changes to Table 1.

If the Codex commodity standard includes Table 3 additives, it is important to determine if the food category associated with the commodity standard is included in the Annex to Table 3. If it is, any Table 3 additive would need to be included in Tables 1 and 2 of the GSFA. If it is not, then there may be relevant changes to Table 3 and amendments to the “References to Commodity Standards for GSFA Table 3 Additives”.

The Decision Tree should be used to decide the appropriate approach to include each food additive provision in a Codex commodity standard into the GSFA.

#### Other resources available to assist Commodity/Regional Committees

A database of food additive specifications with their current ADI status, the year of their most recent JECFA evaluation, their assigned INS numbers, etc. are available in English at the JECFA website at FAO <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>. The database has a query page and background information in English, French, Spanish, Arabic and Chinese.

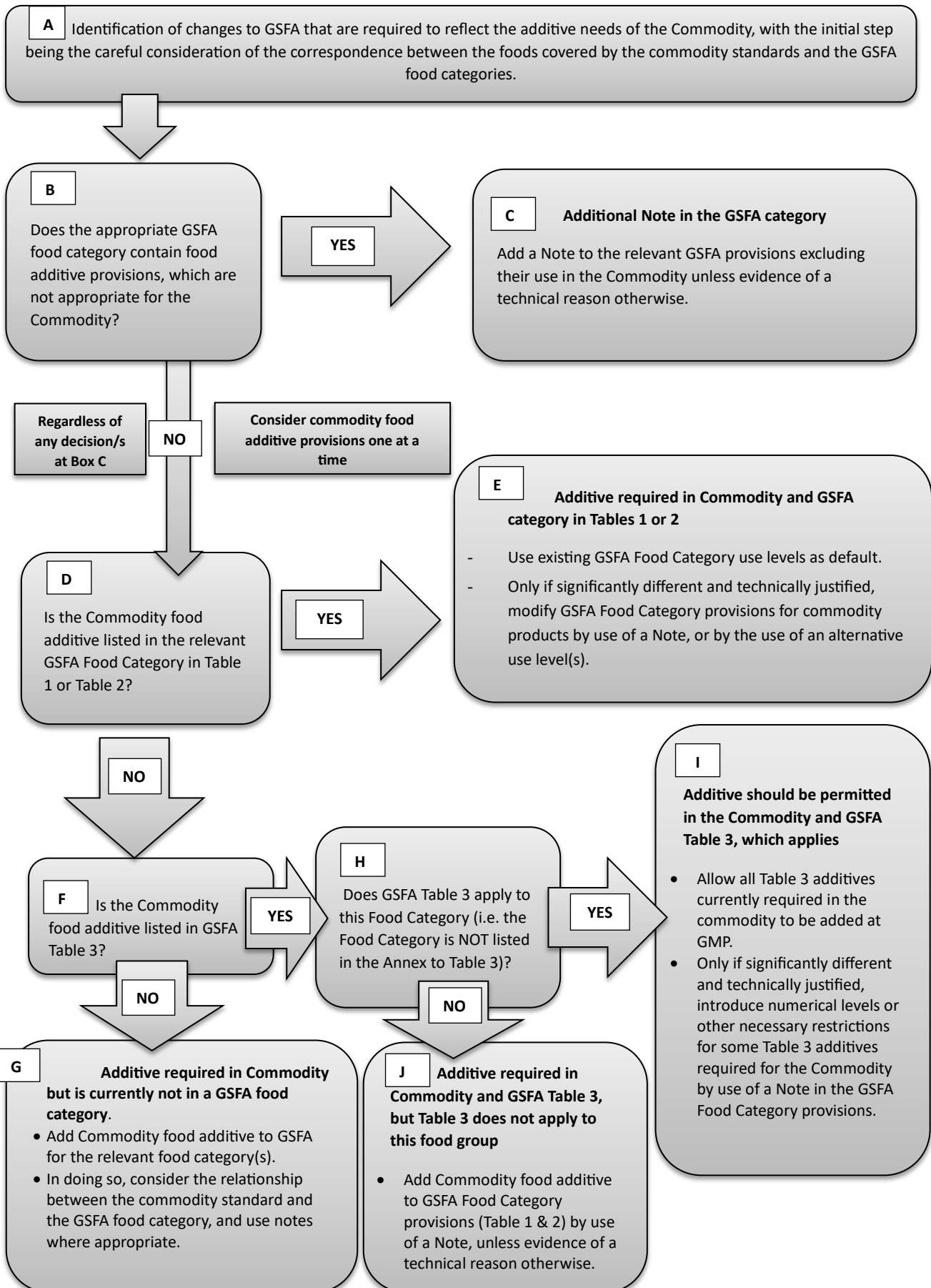
The FAO also host a searchable GSFA database through the Codex Alimentarius website at <http://www.fao.org/gsfonline/index.html>. The database has a query page and is searchable in English, French, Spanish and Chinese.

The Food Category System for food additives is hierarchical and is at Annex B of the GSFA (CODEX STAN 192-1995) and is also accessible through the GSFA database listed above.

The following documents may also assist the corresponding Commodity/Regional Committees:

- a) CCNFSDU Framework for appraising the Technological Need for Food Additives (CCNFSDU Information Document) – INF\_NFSDU20\_e.pdf
- b) Proposed Food Additive Provisions in Standards for Fish and Fishery Products - CX/FFP 11/31/13

**DECISION TREE FOR PROPOSED AMENDMENTS TO THE GSFA BASED ON THE CONSIDERATION OF THE FOOD ADDITIVE NEEDS OF COMMODITY STANDARDS**



**EXAMPLE OF THE PRESENTATION OF PROPOSED AMENDMENTS TO THE GSFA**

An example of the presentation of amendments to the GSFA by Commodity/Regional Committees is presented below. This is for guidance only. Regarding Table 1 and 2, it is only necessary to propose amendments to Table 2 because consequential changes will be made to Table 1 on the adoption of the provisions.

The Commodity/Regional Committee should identify the appropriate parts of the GSFA and use ~~strike through~~ and **underline/bold** to indicate the proposed changes to the GSFA.

1. PROPOSED AMENDMENTS TO TABLE 1,2 AND 3 OF THE GSFA RELATING TO THE CCNE REGIONAL COMMODITY STANDARDS:

- *Regional Standard for Canned Hummus Tehena (CXS 257R-2007)*

- *Regional Standard for Canned Foul Medames (CXS 258R-2007)*

1.1 PROPOSED AMENDMENTS TO TABLE ONE OF THE GSFA

<b>ACESULFAME POTASSIUM</b>					
INS: 950		Functional Class: Flavour enhancer, Sweetener			
<b>FC No.</b>	<b>Food Category</b>	<b>Max Level</b>	<b>Notes</b>	<b>Step/Year Adopted</b>	<b>Recommendation</b>
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	350 mg/kg	188, 478, XS57, <b><u>XS257R,</u></b> <b><u>XS258R</u></b>	2024	Endorse

1.2 PROPOSED AMENDMENTS TO TABLE TWO OF THE GSFA

<b>Food Category Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds</b>					
<b>Additive</b>	<b>INS</b>	<b>Step/Year adopted</b>	<b>Max Level</b>	<b>Notes</b>	<b>Recommendation</b>
ACESULFAME POTASSIUM	950	2024	350 mg/kg	188, 478, XS57, <b><u>XS257R, XS258R</u></b>	Endorse

## 1.3 PROPOSED AMENDMENTS TO TABLE THREE OF THE GSFA

## 1.3.1 PROPOSED AMENDMENTS TO TABLE 3

INS No	Additive	Functional Class	Year Adopted	Specific allowances in the following commodity standards <sup>1</sup>
330	Citric acid	Acidity regulator, Antioxidant, Colour retention agent, Sequestrant	1999	CS 87-1981, CS 105-1981, CS 141-1983, CS 13-1981, CS 57-1981, CS 37-1991, CS 70-1981, CS 90-1981, CS 94-1981, CS 119-1981, CS 302-2011, CS 249-2006, <b>CS 257R-2007</b> , <b>CS 258R-2007</b> , CS 221-2001, CS 273-1968, CS 275-1973, CS 262-2006 (for use in cheese mass only), CS 160-1987 (only for use in heat pasteurized products to maintain the pH at less than or equal to 4.6, and in heat sterilized products), CG 95-2022
501(i)	Potassium carbonate	Acidity regulator, Stabilizer	1999	CS 87-1981, CS 105-1981, CS 141-1983, CS 249-2006, CS 221-2001, CS 250-2006, CS 251-2006, CS 252-2006, <b>CS 257R-2007</b> , CS 273-1968, CS 275-1973, CS 207-1999, CS 262-2006 (as anticaking agent only, see functional class table in CXS 262-2006), CS 281-1971, CS 282-1971, CS 290-1995
500(i)	Sodium carbonate	Acidity regulator, Anticaking agent, Emulsifying salt, Raising agent, Stabilizer, Thickener	1999	CS 87-1981, CS 105-1981, CS 141-1983, CS 249-2006, CS 221-2001, CS 250-2006, CS 251-2006, CS 252-2006, <b>CS 257R-2007</b> , CS 273-1968, CS 275-1973, CS 207-1999, CS 253-2006 (see functional class table and footnote), CS 281- 1971, CS 262-2006 (for use in cheese mass only), CS 282-1971, CS 290-1995

<sup>1</sup> This column only lists commodity standards that allow specific Table 3 additives. If a commodity standard allows Table 3 additives on a general basis or based on functional class, that information is contained in the "References to Commodity Standards for GSFA Table 3 Additives"

## 1.3.2 PROPOSED AMENDMENTS TO REFERENCES TO COMMODITY STANDARDS FOR GSFA TABLE 3 ADDITIVES

04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds
	<b>Only certain Table 3 food additives (as indicated in Table 3) are acceptable for use in foods conforming to the standard.</b>
<b>Codex Standards</b>	<b><u>Canned Humus with Tehena (Near East) (CXS 257R-2007)</u></b> <b><u>Canned Foul Medames (CXS 258R-2007)</u></b>