

# 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-first Session, The Hague, The Netherlands, 22-26 March 1999*

#### **CONSIDERATION OF THE CODEX GENERAL STANDARD FOR FOOD ADDITIVES: PROPOSED DRAFT GUIDELINE FOR THE DEVELOPMENT OF MAXIMUM LEVELS OF USE FOR FOOD ADDITIVES WITH NUMERICAL DAILY INTAKES (ANNEX A)**

#### **INTRODUCTION**

1. At the Twenty-First Session of the Codex Committee on Food Additives and Contaminants, the Committee considered a paper CX/FAC 89/16 prepared by Dr. W.H.B. Denner of the UK, on Future Activities of the Committee in regard to the establishment and regular review of provisions relating to food additives in Codex Standards and possible mechanisms for the establishment of general provisions for the use of food additives in non-standardized foods. In this paper, several recommendations are made, including recommendations for performing the safety evaluation of food additives. Special attention should be given to recommendations 3 - 6 of the Denner paper concerning the safety evaluation (copy enclosed of this section) and the statement that clear guidelines should be given to Member states which can enable them to understand the procedures.
2. For the purpose of the General Standard for Food Additives (GSFA), levels of use of food additives have to be established through a procedure which assures that the ADI's allocated by JECFA will not be exceeded. In his paper (CX/FAC 89/16), Dr. Denner has recommended the Danish Budget Method as the initial approach for screening the additive intake and the safety aspects thereof. This method will hereinafter be called the Budget Method (BM).
3. In the process of establishing the GSFA and the preamble to the standard, an Annex A covering Guidelines for the Estimation of Appropriate Levels of Use of Food Additives has been elaborated and presented in several papers (CX/FAC 95/4, CL 95/37, ALINORM 95/12A and 96/6). Annex A has included a version of the Budget Method as part of a stepwise screening procedure for the estimation of the safety aspects of the proposed additive use levels.
4. At the 30th meeting of the CCFAC a new proposal for an Annex A with a description of the Budget Method was discussed. The Committee concluded that the document should be redrafted in the light of the discussions and comments received. Denmark agreed to carry out this task.
5. The Budget Method was developed as a simple inexpensive way of assessing proposed food additive maximum use levels to ensure that the ADI for the additive is not exceeded. The method is designed to cover the worst case scenario and therefore exaggerates potential additive intake. The Method is applicable for first step assessing potential maximum additive intake in countries with different eating habits. The Budget Method, however, is not an intake assessment as the method is unsuitable for predicting what consumers are actually ingesting. The Method cannot be used to replace more precise food

additive intake calculations (e.g., based on food consumption surveys), where more precise information is considered necessary.

6. The Budget Method is valid internationally, as it is based on the fact that there is a physiological upper limit to the amount of food and drink, and thus of food additives, that can be consumed each day. By limiting the amount of a food additive used in food, and taking account of these limitations, the intake of the additive can be assured to always be below a given level (e.g., the ADI). The Budget Method includes the following basic assumptions:
  - \* the intake of solid food does not exceed 25 g/kg body weight/day.
  - \* the intake of liquid does not exceed 100 ml/kg body weight/day.

These basic figures are then modified by appropriate factors according to likely occurrence of a given additive in the diet as described in more details in Appendix I to this document.

7. At the 30th session of CCFAC several non-western delegations raised concerns about a western-diet bias in the Budget Method. In relation to this concern it is important to bear in mind that basically the Budget Method is related to consumption of solid food and beverage respectively and not to one specific dietary pattern.
8. Furthermore at the 30th session of CCFAC, the need for guidance on the implication of individual geographical dietary pattern on the terms 'half', 'fourth' and 'eighth' of solid food was clearly indicated. It was also suggested in this relation to include the Regional Diets elaborated in the framework of GEMS/FOOD in the considerations. However the GEMS/FOOD regional diets are elaborated as a tool for estimating intake of pesticides and as a result of that its detailed list of food of food commodities is not totally compatible with the GSFA Food Categorization System and in addition it does not include full information on intake of beverages.
9. However the total intakes of major food groups, such as 'Cereals, roots and tubers', 'Fruit', 'Fish, seafood, eggs, meat and offal' calculated from the GEMS/FOOD regional diets give a valuable indication of the average dietary pattern in the individual regions which can be used for the interpretation of the terms 'half', 'fourth' and 'eighth' of solid food used in the Budget Method. The calculated total intake of major food groups for the five regional diets are shown in Appendix II to this document.
10. In order to facilitate the understanding on how to use the Budget Method as a first screening tool some examples are given in annex III to this document.

**DRAFT**  
**CODEX GENERAL STANDARD OF FOOD ADDITIVES**  
**ANNEX A**

**GUIDELINES FOR THE ESTIMATION OF APPROPRIATE LEVELS OF USE OF FOOD ADDITIVES**

This annex is intended as a guidance to screen proposals for use of additives based on consideration of their maximum use level and the physiological upper limit to the amount of food and drink that can be consumed each day. The Annex is not intended for allocating provisions for the use of an additive and cannot be used for calculating accurate additive intakes.

**I. FOOD ADDITIVE, BASIC PRINCIPLES FOR CALCULATION ON USE LEVELS.**

***Guideline 1.***

The levels and quantities of food additives used in the Budget Method calculations should be expressed on the same basis as the substances on which the ADI was allocated (e.g., an acid or its salts). For foods sold as concentrates or powders intended for reconstitution before consumption, the Budget calculation on the food additive use levels should be performed on the ready-to-eat product.

**II. ESTIMATION OF THE SAFETY ASPECTS ON USE LEVELS - FOOD ADDITIVES WITH NO NUMERICAL ADI.**

***Guideline 2.***

***FOOD ADDITIVES WITH ADI "NOT SPECIFIED"***

When an additive has been allocated an ADI "not specified"<sup>1</sup> it could in principle, be allowed for use in foods in general with no limitation other than in accordance with Good Manufacturing Practices (GMP). It should, however, be born in mind that ADI not specified does not mean that unlimited intake is acceptable. The term is used by JECFA in case where "on the basis of the available data (chemical, biochemical, toxicological, and other) the total daily 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 the Committee, represent a hazard to health"<sup>1</sup>. If, therefore, a substance is used in larger amounts and/or in a wider range of foods than originally envisaged by JECFA it may be necessary to consult JECFA to ensure that the new uses fall within the evaluation. For example a substance may have been evaluated as a humectant without including a later use as a bulk sweetener, which could give considerable higher intake.

***Guideline 3.***

***FOOD ADDITIVES EVALUATED AS "ACCEPTABLE" FOR CERTAIN PURPOSES***

In some cases, JECFA has been unable to allocate an ADI but nevertheless found a specific use of a substance acceptable. In such cases, the additive in question should only be authorized in accordance with the conditions specified. In case of any other reported uses CCFAC should request JECFA to re-evaluate the additive in question in light of the new information on uses.

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<sup>1</sup> *Principles for the safety assessment of food additives and contaminants in food.* Geneva, World Health Organization, 1987 (Environmental Health Criteria, No. 70), p. 83.

### **III. ESTIMATION OF THE SAFETY ASPECTS ON USE LEVELS - FOOD ADDITIVES WITH NUMERICAL ADI.**

#### ***Guideline 4,***

##### ***FRACTIONS OF THE ADI TO BE USED FOR SOLID FOOD AND BEVERAGES RESPECTIVELY***

If an additive is proposed for use in both solid food and in beverages the full ADI cannot be used for both for uses in solid food and uses in beverages. It is therefore necessary to allocate a fraction of the ADI to each of the applications. As a first approach, it may be appropriate to assume that one-half of the ADI is allocated to each solid and liquid foods. However, in special cases other fractions may be more appropriate as long as the sum of the fractions does not exceed the figure for the ADI (e.g.  $F_S = 1/4$  and  $F_B = 3/4$ ;  $F_S = 1/6$  and  $F_B = 5/6$ ), where  $F_S$  is the fraction for use in solid food and  $F_B$  is the fraction for use in beverages). If the additive is used only in solid food, then  $F_S = 1$  and  $F_B = 0$  and if the additive is used only in beverages, then  $F_S = 0$  and  $F_B = 1$ .

#### **IIIA FOOD ADDITIVE USES IN SOLID FOOD**

##### **GUIDELINE 5,**

###### ***USE LEVELS BELOW $F_S \times ADI \times 40$***

If the proposed use levels are below  $F_S \times ADI \times 40$ , these food additive provisions could be suitable in food in general.

##### **GUIDELINE 6,**

###### ***USE LEVELS BELOW $F_S \times ADI \times 80$***

If the proposed use levels are below  $F_S \times ADI \times 80$  they are acceptable provided the daily consumption of the foods containing the additive will usually not exceed half of the assumed maximum total solid food intake (i.e. 12.5 g/kg bw/day).

##### ***Guideline 7,***

###### ***USE LEVELS BELOW $F_S \times ADI \times 160$***

If the proposed use levels are below  $F_S \times ADI \times 160$  they are acceptable provided the daily consumption of the foods containing the additive will usually not exceed one fourth of the assumed maximum total solid food intake (i.e., 6.25 g/kg bw/day).

##### **GUIDELINE 8,**

###### ***USE LEVELS BELOW $F_S \times ADI \times 320$***

If the proposed use levels are below  $F_S \times ADI \times 320$  they could be accepted provided the daily consumption of the foods containing the additive will usually not exceed one eighth of the assumed maximum total food intake (i.e., 3.13 g/kg bw/day).

##### **GUIDELINE 9,**

###### ***USE LEVELS ABOVE $F_S \times ADI \times 320$***

If the proposed levels are higher than  $F_S \times ADI \times 320$  they should only be accepted for products where calculation of potential intake from all proposed uses will show that exceeding the ADI is unlikely, or if estimation of the intake of the additive based on more exact intake estimates methods show that the use levels are acceptable (e.g., food consumption surveys)

**III B FOOD ADDITIVE USES IN BEVERAGES*****Guideline 10,******USE LEVELS BELOW  $F_L \times ADI \times 10$*** 

If the proposed levels are below  $F_L \times ADI \times 10$ , the additive could be accepted for use in all beverages in general.

***Guideline 11,******USE LEVELS BELOW  $F_L \times ADI \times 20$*** 

If the proposed use levels are below  $F_L \times ADI \times 20$  they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed half of the assumed maximum total intake of beverage (i.e., 50 ml/kg bw/day).

***Guideline 12,******USE LEVELS BELOW  $F_L \times ADI \times 40$*** 

If the proposed use levels are below  $F_L \times ADI \times 40$  they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed a fourth of the assumed maximum total intake of beverage (i.e., 25 ml/kg bw/day).

***Guideline 13,******USE LEVELS BELOW  $F_L \times ADI \times 80$*** 

If the proposed use levels are below  $F_L \times ADI \times 80$  they could be accepted provided the daily consumption of beverages containing the additive will usually not exceed an eighth of the assumed maximum total intake of beverage (i.e., 12.5 ml/kg bw/day).

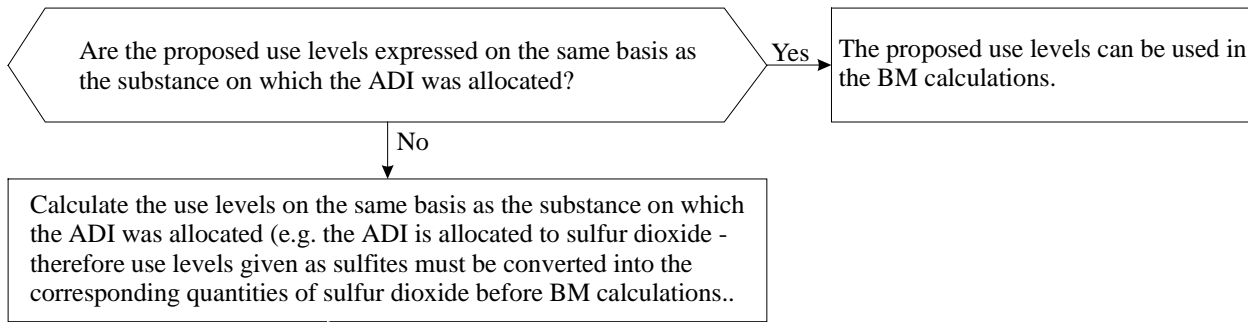
***Guideline 14,******USE LEVELS ABOVE  $F_L \times ADI \times 80$*** 

Levels above  $F_L \times ADI \times 80$  should only be accepted for products where calculation of potential intake will show that exceeding the ADI is unlikely (e.g., strong alcoholic beverages).

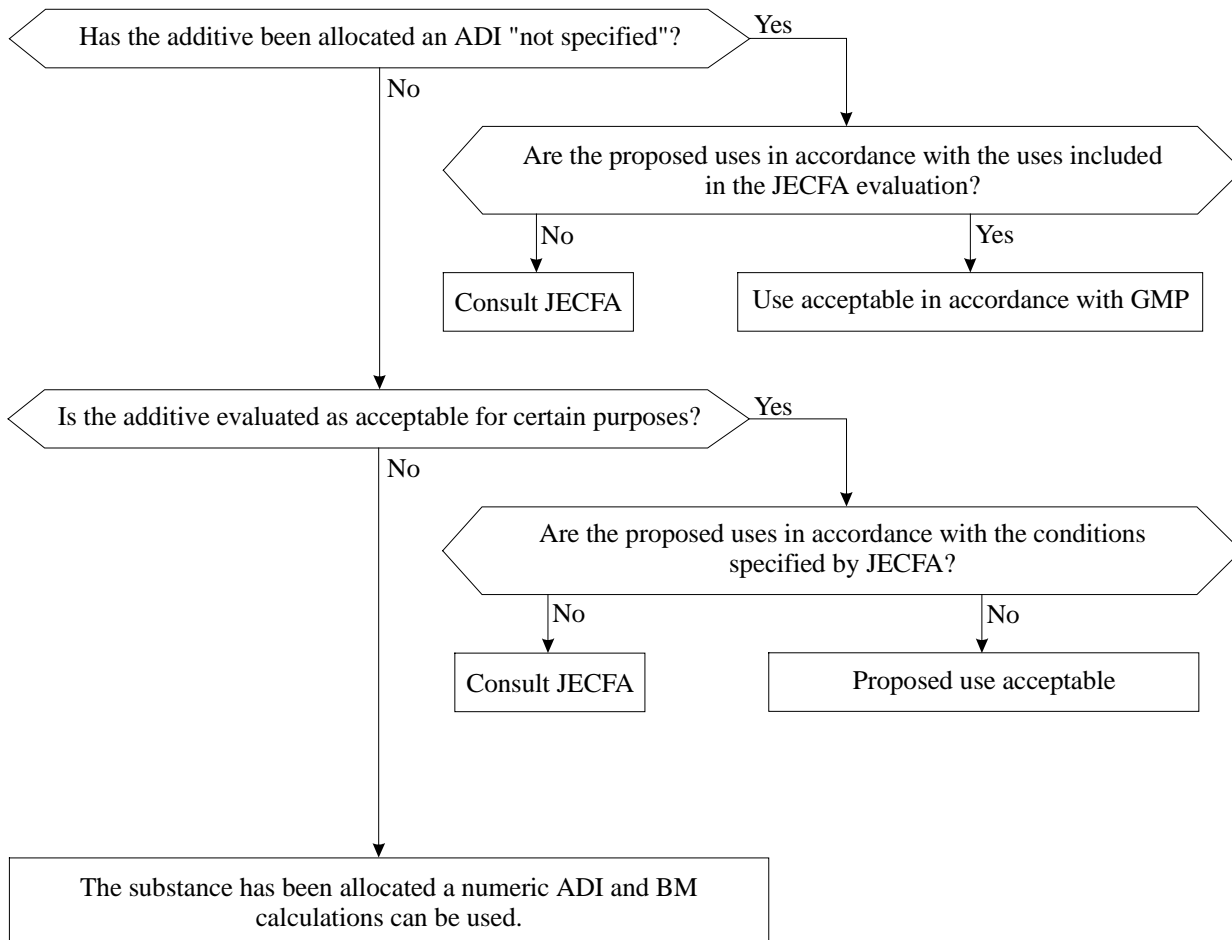
**Appendix I**

**A Flow-Sheet Presentation of the Budget Method (BM)**

**Guideline 1 - Basic principles for calculation on use levels**

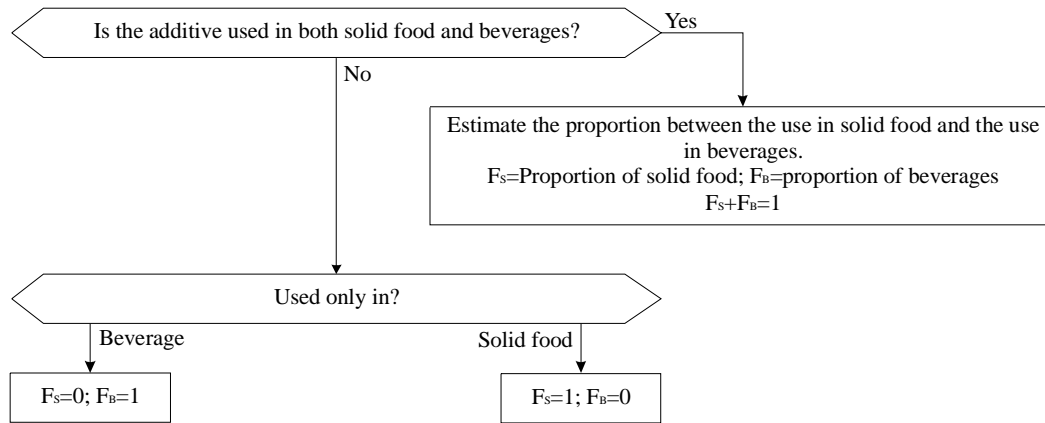


**Guidelines 2 and 3 - The food additive has not been allocated a numerical ADI**

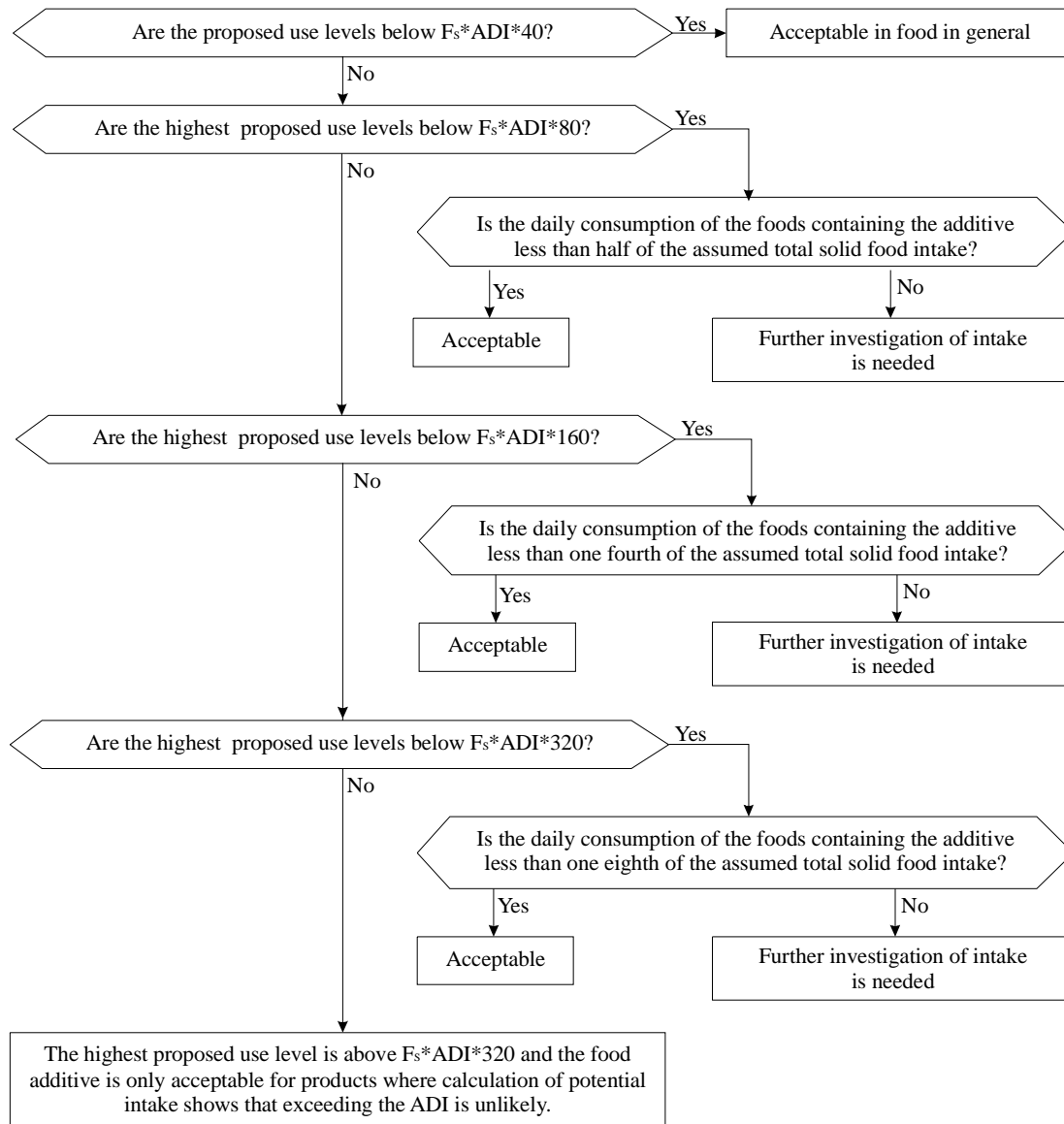


**Guidelines 4 - Fractions of the ADI to be used for solid food and beverages respectively**

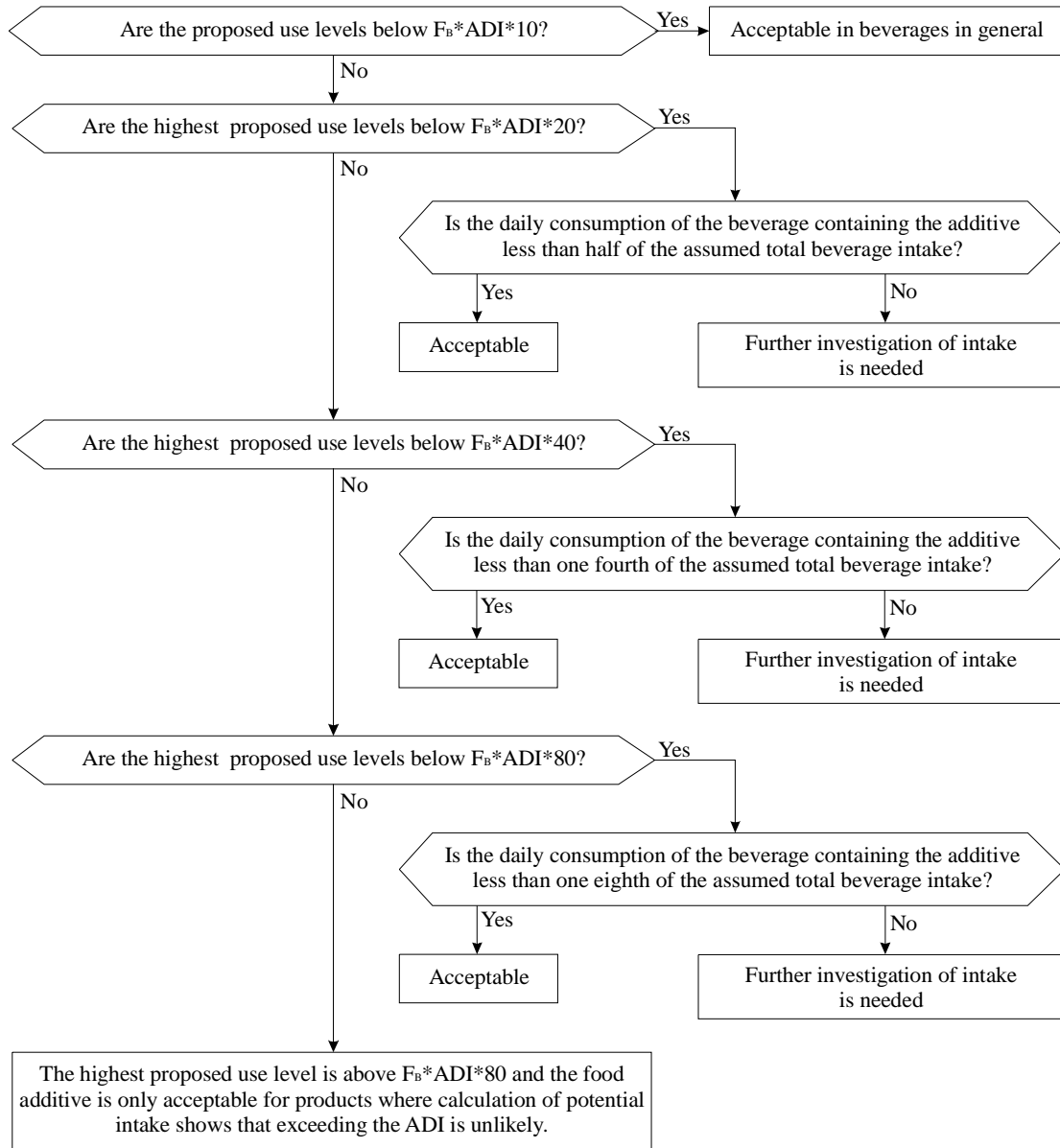
(Establishing the factors  $F_S$  and  $F_B$  to be used in the calculations for solid food and beverages respectively)



**Guidelines 5, 6, 7, 8 and 9 - Food additive uses in solid food**



**Guidelines 10, 11, 12, 13 and 14 - Food additive uses in beverages**





## Appendix II

**Regional diets - Calculated intakes of major food groups**  
**Based on GEMS FOOD regional diets**

The table shows the total intake of major food groups. The figures are calculated as % (w/w) of total intake of solid food.

	<b>Middle Eastern Diet</b>	<b>Far Eastern Diet</b>	<b>African Diet</b>	<b>Latin American Diet</b>	<b>European/Western Diet</b>
<b>Milk and milk products</b>	10.7	3.4	4.2	12.3	18.8
<b>Oils and fats</b>	3.4	1.7	2.3	2.0	2.7
<b>Fruits</b>	17.1	6.8	8.6	19.1	12.4
<b>Nuts and oilseeds</b>	0.7	3.0	1.3	2.7	1.0
<b>Vegetables</b>	10.0	8.6	7.0	14.1	14.7
<b>Roots and tubers</b>	5.0	11.4	31.7	11.7	13.5
<b>Pulses</b>	1.6	1.7	1.7	1.5	0.5
<b>Cereal and grains</b>	34.9	47.6	31.4	18.5	12.6
<b>Meat, fish and eggs</b>	8.2	10.0	7.3	10.0	17.2
<b>Sugars and honey</b>	7.7	5.3	4.2	7.6	5.9

**Example on how to use the regional diet estimate proportions of intake**

Estimation on staple foods which will represent intake of approximately 'half of solid food':

	<b>Middle Eastern Diet</b>	<b>Far Eastern Diet</b>	<b>African Diet</b>	<b>Latin American Diet</b>	<b>European/Western Diet</b>
<b>Milk and milk products</b>	✓			✓	✓
<b>Oils and fats</b>					
<b>Fruits</b>					
<b>Nuts and oilseeds</b>					
<b>Vegetables</b>					
<b>Roots and tubers</b>	✓	✓	✓	✓	✓
<b>Pulses</b>					
<b>Cereal and grains</b>	✓	✓	✓	✓	✓
<b>Meat, fish and eggs</b>					
<b>Sugars and honey</b>					
<b>Calculated proportion of solid food (%)</b>	51	59	63	43	45

## Appendix III

**Examples on how to use the Budget Method as a first screening**

Below is listed some detailed examples on screening carried out on certain substances included in the draft GSFA table 1 and table 2.

**Tannic Acid (Tannins, Food Grade)**

181 Tannic Acid (Tannins, Food Grade)

**Function:** Colour

**ADI:** Acceptable - as a filtering aid where the application of GMP ensures that it is removed from food after use.

**Budget considerations:**

Guideline 1: no need.

Guideline 2: ADI is not 'not specified'.

Guideline 3: the use as colour is not in accordance with the JECFA evaluation.

**Conclusion:** Uses not in accordance with conditions specified in the JECFA evaluation CCFAC should request JECFA to re-evaluate the substance in the light of new information on uses.

**CYCLODEXTRIN, BETA-**

459 Cyclodextrin, Beta-

**Function:** Adjuvant, Binder, Stabilizer

**ADI:** 5 mg/d/kg bw

**Used only in beverages, significant uses:** 500 mg/l

**Budget considerations:**

Guideline 1: no need.

Guideline 2 and 3: ADI is numeric.

Guideline 4: the additive is used only in beverage  $F_B = 1$

Guideline 5 to 9: not applicable.

Guideline 10: significant maximum use level is not below  $F_B \times ADI \times 10 = 50$  mg/l

Guideline 11: significant maximum use level is not below  $F_B \times ADI \times 20 = 100$  mg/l

Guideline 12: significant maximum use level is not below  $F_B \times ADI \times 40 = 200$  mg/l

Guideline 13: significant maximum use level is not below  $F_B \times ADI \times 80 = 400$  mg/l

Guideline 14: significant maximum use level is above  $F_B \times ADI \times 80 = 800$  mg/l the substance is widely used in beverages

**Conclusion:** Intake should be further investigated or uses should be revised.

**AZODICARBONAMIDE**

927a Azodicarbonamide

**Function:****ADI:** 45 mg/d/kg bw**Used only in solid food, significant uses:** 45 mg/kg**Budget considerations:**

Guideline 1: no need.

Guideline 2 and 3: ADI is numeric.

Guideline 4: the additive is used only in solid food  $F_S = 1$ Guideline 5: significant maximum use level is below  $F_S \times \text{ADI} \times 40 = 1800$  mg/kg.**Conclusion:** Acceptable.**ADIPATES**

355 Adipic Acid

356 Sodium Adipate

357 Potassium Adipate

359 Ammonium Adipate

**Function:** Acidity Regulator, Firming Agent, Raising Agent**ADI:** 5 mg/d/kg bw**Used both in solid food and beverages,****significant uses in solid food:** 6000 mg/kg**significant uses in beverage:** 10000 mg/l**Budget considerations:**

Guideline 1: no need.

Guideline 2 and 3: ADI is numeric.

Guideline 4: the additive is widely used in both solid food and beverage. Therefore  $F_S = 0.5$  and  $F_B = 0.5$ Guideline 5: significant maximum use level is not below  $F_S \times \text{ADI} \times 40 = 100$  mg/kg.Guideline 6: significant maximum use level is not below  $F_S \times \text{ADI} \times 80 = 200$  mg/kgGuideline 7: significant maximum use level is not below  $F_S \times \text{ADI} \times 160 = 400$  mg/kg.Guideline 8: significant maximum use level is not below  $F_S \times \text{ADI} \times 320 = 800$  mg/kg.Guideline 9: significant maximum use level is above  $F_S \times \text{ADI} \times 320 = 800$  mg/kg. The substance is widely used in solid food.Guideline 10: significant maximum use level is not below  $F_B \times \text{ADI} \times 10 = 25$  mg/lGuideline 11: significant maximum use level is not below  $F_B \times \text{ADI} \times 20 = 50$  mg/lGuideline 12: significant maximum use level is not below  $F_B \times \text{ADI} \times 40 = 100$  mg/lGuideline 13: significant maximum use level is not below  $F_B \times \text{ADI} \times 80 = 200$  mg/lGuideline 14: significant maximum use level is above  $F_B \times \text{ADI} \times 80 = 200$  mg/l, the substance is widely used in beverages.

**Conclusion:** Intake from both solid food and beverages should be further investigated or uses should be revised.

## NITRATES

251 Sodium Nitrate

252 Potassium Nitrate

**Function:** Colour Retention Agent, Preservative

**ADI:** 3.7 mg/d/kg bw

**Used both in solid food and beverages,**

**significant uses in solid food:** 365 mg/kg

**significant uses in beverage:** 73mg/l

### **Budget considerations:**

Guideline 1: no need.

Guideline 2 and 3: ADI is numeric.

Guideline 4: the additive is used in both solid food and beverage. The use in solid food include several food categories, the use in beverage is only in spirituous beverage, therefore  $F_S = 0.9$  and  $F_B = 0.1$

Guideline 5: significant maximum use level is not below  $F_S \times ADI \times 40 = 133$  mg/kg.

Guideline 6: significant maximum use level is not below  $F_S \times ADI \times 80 = 266$  mg/kg

Guideline 7: significant maximum use level is below  $F_S \times ADI \times 160 = 533$  mg/kg, the uses cover more than 1/4 of solid food.

Guideline 10: significant maximum use level is not below  $F_B \times ADI \times 10 = 3.7$  mg/l

Guideline 11: significant maximum use level is not below  $F_B \times ADI \times 20 = 7.4$  mg/l

Guideline 12: significant maximum use level is not below  $F_B \times ADI \times 40 = 14.8$  mg/l

Guideline 13: significant maximum use level is not below  $F_B \times ADI \times 80 = 29.6$  mg/l

Guideline 14: significant maximum use level is above  $F_B \times ADI \times 80 = 29.6$  mg/l, the substance is only used in spirituous beverages, the ADI will only be exceeded by an intake of more than 3000 ml of spirituous beverages.

**Conclusion:** Intake from solid food should be further investigated or uses should be revised.