



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Forty-fourth Session

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### DISCUSSION PAPER ON USE OF NOTE 161 IN THE GSFA

(Prepared by South Africa with the assistance of Argentina, Australia, Brazil, Chile, Denmark, Ecuador, European Union, Ghana, New Zealand, Japan, Malaysia, Mexico, Norway, Thailand, United Kingdom, United States of America, CCC, IACM, ICGMA and ISA)

#### **Background**

1. The 43<sup>rd</sup> Session of the Codex Committee on Food Additives (CCFA), agreed to establish an eWG, led by South Africa, and working in English only, to continue working on a discussion paper on the application of Note 161 (“Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble”), and in particular to formulate a discussion document to facilitate a uniform implementation of Section 3.2 of the Preamble of the GSFA to address the use of Note 161.
2. The 43<sup>rd</sup> CCFA could not reach consensus on the use of Note 161. Some delegations expressed concern over the implications of the use of Note 161 on trade, and that the use of Note 161 undermines the international standard-setting efforts of Codex and the value of Codex’s science-based decisions. Other delegations were of the opinion that the use of Note 161 was important, particularly because, in their view, the procedures established in Section 3.2 of the Preamble of the GSFA and in the Procedural Manual had not been rigorously followed.<sup>1</sup>
3. The delegations of Argentina, Australia, Brazil, Chile, Denmark, Ecuador, European Union, Ghana, New Zealand, Japan, Malaysia, Mexico, Norway, Thailand, United Kingdom, United States of America, CCC, IACM, ICGMA and ISA expressed interest in participating in this eWG, and the delegations of Australia, European Union, Japan, New Zealand, United Kingdom, United States of America, CCC, IACM, ICGMA and ISA actively participated in the preparation of this discussion paper.

#### **Analysis of the Use of Note 161**

4. Up to 2010, Note 161 had been assigned to provisions for sweeteners and colours only in the GSFA. In 2011, no provisions with Note 161 were forwarded to, nor adopted by, the 34<sup>th</sup> Codex Alimentarius Commission (CAC)<sup>2</sup>. The occurrence of Note 161 in the adopted (Step 8) provisions for sweeteners and colours has been analyzed from the perspective of the frequency of use of Note 161 over time, and of the food categories where Note 161 is used. These analyses are provided in Annex 1 and Annex 2, respectively.
5. The data in Annex 1 (Table 3) indicates that the use of Note 161 has decreased over time. However, the data in Annex 2 indicate that Note 161 is associated with a variety of food categories for both sweeteners and colours. One notable observation is that a number of these food categories coincide with the Committee’s working lists of food categories in which the use of sweeteners and colours are technologically justified.<sup>3</sup> In particular, Note 161 is associated with a significant number of provisions for sweeteners in food categories for which the Committee has already determined sweeteners are technologically justified (i.e., all food categories listed in Annex 2, Table 1 except 01.6.1, 04.1.2.1, 04.1.2.2, 04.2.2.1, 04.2.2.2, 04.2.2.4, 04.2.2.8, 05.1.1, 08.2.2, 08.3.2, and 09.2.4.1). Similarly, Note 161 is associated with a significant number of colour provisions in food categories for which the Committee has determined that the use of colours is

<sup>1</sup> REP 11/FA, paras. 107 – 114.

<sup>2</sup> REP 11/FA, Appendix III, REP 11/CAC, Appendix III.

<sup>3</sup> CX/FA 08/40/5, Part 2, Appendix I and CX/FA 11/43/7 Appendix, respectively.

technologically justified (i.e., all food categories listed in Annex 2, Table 2 except 04.2.2<sup>4</sup>, 07.0<sup>5</sup>, 07.1.3, 07.1.5, 07.1.6, and 10.2).

### **Discussion of the Need for Note 161 in Relation to the Preamble to the GSFA and Procedural Manual**

6. Some Codex Members are of the view that Note 161 is necessary to account for deviations from the GSFA based on national practices, climatic differences, and/or for the purpose of not misleading the consumer, and not necessarily on food safety concerns. Members advocating Note 161 have also requested its use because, in their view, Section 3.2 of the Preamble to the GSFA<sup>6</sup> has not been rigorously applied.

7. Other Codex Members are of the view that Note 161 is being used to create exceptions to the GSFA that are unnecessary and inappropriate. This is illustrated, for example, by the finding (Annex 2) that a number of food categories that have Note 161 associated with them coincide with the Committee's working lists of food categories in which the use of sweeteners and colours are technologically justified.

8. The Preamble to the GSFA provides general guidance to national authorities when interpreting the acceptable maximum use levels in the GSFA to account for differences in national practices relating to food additive uses, while neither imposing national practices on the global community nor preventing progress on the GSFA. Specific sections of the Preamble were elaborated to account for regional and cultural practices in the use of food additives globally, while providing national authorities with guidance to determine when the specific use of an additive is consistent with the GSFA.

9. In particular, Section 3 of the Preamble, as a whole, is intended to provide national authorities with guidance in the interpretation of the acceptable maximum use levels in the GSFA. This Section is not intended to be criteria for entering acceptable maximum use levels into the GSFA. Importantly, Section 3.1 (Food Additive Safety) provides general principles for how the acceptable maximum use levels in the GSFA should be considered at the national level in terms of food safety. Section 3.2 (Justification For the Use of Additives) provides general principles for national authorities to consider when evaluating whether the specific use of an additive is technologically needed. Section 3.3 (Good Manufacturing Practices) provides additional information for national authorities to consider when evaluating whether the specific use of an additive is consistent with the principles of good manufacturing practices. Section 5 (Food Category System) clarifies that the GSFA's food category descriptors are not intended for use as legal product designations. A significant number of members of the eWG are of the opinion that these Sections of the Preamble provide national authorities with adequate guidance for interpreting the acceptable maximum use levels in the GSFA, and render use of Note 161 unnecessary. The Codex Procedural Manual describes the process for the entry and review of food additive provisions in the GSFA.<sup>7</sup> This text describes the data and information that should be submitted to CCFA when requesting the addition or revision of provisions in the GSFA, as well as the decisions required to establish acceptance or rejection of these proposals. In particular, the process explicitly considers the criteria in Section 3.2 of the Preamble by asking the question "Does the food additive use meet the criteria of Section 3.2 of the Preamble of the General Standard for Food Additives?"

10 The Codex Procedural Manual, in the "Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process," provides guidance for consideration of factors that are not science-based in developing Codex standards (Annex 3). Some Codex Members have noted that the use of Note 161 is inconsistent with this guidance, in particular with the need to take into account only those factors that can be accepted on a worldwide basis when developing a Codex standard. However, it should be recognized that the

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<sup>4</sup> Although the broad category 04.2.2 is not listed in the Appendix to CX/FA 11/43/7, the sub-categories 04.2.2.2, 04.2.2.3, 04.2.2.4, 04.2.2.5, 04.2.2.7 and 04.2.2.8 are listed.

<sup>5</sup> Although the broad categories 07.0 and 07.1 are not listed in the Appendix to CX/FA 11/43/7, the sub-categories 07.1.2, 07.1.4, (and its sub-categories 07.2.1, 07.2.2, and 07.2.3) are listed.

<sup>6</sup> Section 3.2 of the Preamble of the GSFA sets out the criteria under which the use of food additives are justified. These criteria include when the use has an advantage, does not present an appreciable health risk to consumers, does not mislead consumers, serves a technological function set out by Codex, and meets objectives that cannot be achieved by other means that are economically and technologically practicable. These objectives, which are provided in paragraphs (a) – (d) of Section 3.2, include: preserving the nutritional quality of food, providing necessary ingredients for foods manufactured for consumers with special dietary needs, enhancing the stability of food or improving its organoleptic properties, and providing aids in the manufacture of food.

<sup>7</sup> "Procedures for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives" (Codex Procedural Manual, 20<sup>th</sup> Ed., pp. 55-61)

“Statements of Principle” also acknowledges that a national authority or geographic region may have legitimate concerns, but they may not be relevant worldwide, and therefore, not applicable to the Codex standard.

### **Options Discussed by the eWG**

11. As a way forward, the eWG discussed three possible options. The options and the discussions by the eWG are summarized below.

#### **Option 1**

12. Delete Note 161 from all provisions in the GSFA. This note is no longer to be used in the GSFA. Acknowledge that:

- (i) Codex currently has guidance for consideration of other factors that are not science-based;<sup>8</sup> and
- (ii) Section 3 of the Preamble provides national authorities with guidance on the interpretation of acceptable maximum use levels in the GSFA. It is not intended as criteria for entering acceptable maximum use levels in the GSFA.

#### **Comments received on Option 1**

13. Most of the comments received support this option. One eWG member specifically noted the guidance provided in the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors Are Taken Into Account*, and the purpose of Section 3 of the Preamble to the GSFA should, address the concerns that have been raised to justify the use of Note 161. One eWG member observed that discontinuation of the use of Note 161 would require the removal of Note 161 from 399 provisions in the GSFA. However, if CCFA agrees in principle that Note 161 is not necessary, then it can be easily removed *en masse* from the GSFA, as there is no need to review the removal of the note provision by provision. One eWG member opposed this option, stating that it was not within the mandate of the eWG. This is correct if the mandate is strictly interpreted as developing criteria for the uniform implementation of the principles in the Preamble, as provided in Option 3. However, a broader interpretation of the eWG’s mandate indicates that there are tools for implementation already in place, for example in the existing text in the Procedural Manual and Preamble to the GSFA, as discussed in paragraphs 8 and 9, above.

#### **Option 2**

14. Revise the text of Note 161 to clarify that it is intended as an indication that some countries have more restrictive measures than the provision in the GSFA.

#### **Comments received on Option 2**

15. This option was not generally supported by the eWG. One member noted that this option would have little effect on the use of the GSFA, as it merely provides information to users. Another eWG member observed that revising the text could change the meaning of Note 161, so that it became a clarification of current practice, resulting in the GSFA taking on a quasi-monitoring function, which is not the purpose of the GSFA. They further noted that, there may be countries who legitimately maintain more restrictive measures than those in the GSFA, but who choose not to indicate this by invoking Note 161. In their view, such an inconsistent use of Note 161 would render it almost meaningless. Finally, they indicated that the use of Note 161 might increase. Another eWG member stated that this option was not within the mandate of the eWG. One eWG member opposed this option, stating that it was not within the mandate of the eWG, as discussed for Option 1.

#### **Option 3**

16. Retain Note 161, either with the current text or revised text, and develop procedures and data/information requirements for the inclusion of Note 161 in the GSFA. Agree that these procedures and requirements should limit the use of Note 161 as much as possible.

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<sup>8</sup> “Statements of Principle Concerning the Role of Science in the Codex Decision--Making Process and the Extent to Which Other Factors Are Taken Into Account” (Codex Procedural Manual, 20<sup>th</sup> Ed., pp. 209-210)

**Comments received on Option 3**

17. Two eWG members supported this option. One indicated that it was consistent with the mandate of the eWG.

**Recommendations to the CCFA**

18. Taking into consideration the comments received by the eWG, the CCFA should consider Option 1 and Option 3 for further discussion.

19. In considering Option 1, the CCFA would need to confirm the principles outlined in the Option, and agree to remove Note 161 from the provisions in the GSFA *en masse*.

20. In considering Option 3, the CCFA would need to continue its work to develop the procedures and data/information requirements for those cases where Note 161 should be included in the GSFA. In doing so, the CCFA should consider the following in its discussion:

- (i) Whether pursuing this Option is an efficient use of the CCFA's resources, given that previous eWGs and the CCFA have discussed this issue, and have sought to develop such procedures and requirements without progress.
- (ii) Whether the further use of Note 161 should continue to be suspended until such procedures and requirements are developed.
- (iii) Whether the current text of Note 161 is appropriate, or could be revised to better clarify its purpose.
- (iv) Whether the development of such procedures and requirements would be considered as new work by CCFA.

## Annex 1

**Analysis of the Use of Note 161 up to 2011**

Up to 2010, Note 161 had been assigned to provisions for colours and sweeteners only in the GSFA. In 2011, the 43<sup>rd</sup> CCFA did not forward any additive provisions with Note 161 for adoption at Step 8 by the 34<sup>th</sup> CAC (REP 11/FA, Appendix III; REP 11/CAC, Appendix III).

The number of adopted (Step 8) provisions in the GSFA for each additive with the functional class of sweetener or colour, respectively, are summarized in the two tables below. In addition, the percent of the total adopted (Step 8) provisions that have Note 161 associated with them are provided for each additive.

<b>Table 1</b>		
<b>SWEETENER</b>	<b>NUMBER OF ADOPTED (Step 8) PROVISIONS WITH NOTE 161</b>	<b>PERCENT OF ALL ADOPTED (Step 8) PROVISIONS WITH NOTE 161</b>
ASPARTAME-ACESULFAME SALT	10	63
ALITAME	13	82
CYCLAMATES	23	68
SACCHARINS	38	63
ACESULFAME POTASSIUM	44	69
ASPARTAME	49	72
NEOTAME	49	77
SUCRALOSE (TRICHLOROGALACTOSUCROSE)	49	77
<b>TOTAL ADOPTED PROVISIONS</b>	<b>275</b>	

<b>Table 2</b>		
<b>COLOUR</b>	<b>NUMBER OF ADOPTED (Step 8) PROVISIONS WITH NOTE 161</b>	<b>PERCENT OF ALL ADOPTED (Step 8) PROVISIONS WITH NOTE 161</b>
IRON OXIDES	1	3
CARMINES	3	4
CARAMEL IV - SULFITE AMMONIA CARAMEL	4	6
CHLOROPHYLLS AND CHLOROPHYLLINS, COPPER COMPLEXES	5	9
GRAPE SKIN EXTRACT	7	11
FAST GREEN FCF	8	22
CAROTENOIDS	9	12
CARAMEL III - AMMONIA CARAMEL	11	14
BRILLIANT BLUE FCF	12	20
SUNSET YELLOW FCF	12	19
PONCEAU 4R (COCHINEAL RED A)	12	25
INDIGOTINE (INDIGO CARMINE)	18	35
ALLURA RED AC	22	42
<b>TOTAL ADOPTED PROVISIONS</b>	<b>124</b>	

Reduction in the Use of Note 161

The use of Note 161 has decreased significantly over the years. The data in Tables 1 and 2 can be grouped by the year of adoption at Step 8. Table 3 summarizes the number of adopted (Step 8) provisions associated with Note 161 from 2007 until 2011 for each additive.

<b>Table 3</b>	
<b>Additive (Grouped by Year of Adoption at Step 8)</b>	<b>Number of Adopted (Step 8) Provisions with Note 161</b>
<b>2007</b>	<b>164</b>
ACESULFAME POTASSIUM	31
ALITAME	13
ASPARTAME	25
CYCLAMATES	20
NEOTAME	31
SACCHARINS	18
SUCRALOSE (TRICHLOROGALACTOSUCROSE)	26
<b>2008</b>	<b>125</b>
ACESULFAME POTASSIUM	13
ASPARTAME	23
CARMINES	3
CYCLAMATES	3
NEOTAME	18
PONCEAU 4R (COCHINEAL RED A)	12
SACCHARINS	19
SUCRALOSE (TRICHLOROGALACTOSUCROSE)	23
SUNSET YELLOW FCF	11
<b>2009</b>	<b>94</b>
ALLURA RED AC	22
ASPARTAME	1
ASPARTAME-ACESULFAME SALT	10
BRILLIANT BLUE FCF	12
CARAMEL III - AMMONIA PROCESS	5
CARAMEL IV - SULFITE AMMONIA PROCESS	2
CAROTENOIDS	2
CHLOROPHYLLS AND CHLOROPHYLLINS, COPPER COMPLEXES	5
FAST GREEN FCF	8
GRAPE SKIN EXTRACT	7
INDIGOTINE (INDIGO CARMINE)	18
IRON OXIDES	1
SUNSET YELLOW FCF	1
<b>2010</b>	<b>16</b>
CARAMEL III - AMMONIA PROCESS	6
CARAMEL IV - SULFITE AMMONIA PROCESS	2
CAROTENOIDS	7
SACCHARINS	1
<b>2011</b>	<b>0</b>
<b>Grand Total</b>	<b>399</b>

## Annex 2

**Analysis of the Use of Note 161 by Food Category**

For the sweeteners and colours listed in Tables 1 and 2 of Annex 1, the food categories corresponding to the adopted (Step 8) provisions that have Note 161 associated with them are tabulated in Table 1 and 2, respectively, below. For each food category, the number of sweeteners or colours that have an adopted (Step 8) provision is also provided.

<b>Table 1 - Sweeteners</b>		
<b>Food Category</b>	<b>Food Category Description</b>	<b>Number of Sweeteners (out of 8) with Adopted (Step 8) Provisions that Contain Note 161</b>
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	8
01.3.2	Beverage whiteners	4
01.4.4	Cream analogues	4
01.5.2	Milk and cream powder analogues	3
01.6.1	Unripened cheese	1
01.6.5	Cheese analogues	5
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	8
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	3
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	7
03.0	Edible ices, including sherbet and sorbet	7
04.1.2.1	Frozen fruit	4
04.1.2.2	Dried fruit	4
04.1.2.3	Fruit in vinegar, oil, or brine	2
04.1.2.4	Canned or bottled (pasteurized) fruit	7
04.1.2.5	Jams, jellies, marmalades	8
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	6
04.1.2.7	Candied fruit	4
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	7
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	7
04.1.2.10	Fermented fruit products	5
04.1.2.11	Fruit fillings for pastries	4
04.1.2.12	Cooked fruit	4
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	4
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	4
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	1
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	5

<b>Table 1 - Sweeteners</b>		
<b>Food Category</b>	<b>Food Category Description</b>	<b>Number of Sweeteners (out of 8) with Adopted (Step 8) Provisions that Contain Note 161</b>
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	4
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	7
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	4
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	4
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	1
05.1.2	Cocoa mixes (syrups)	7
05.1.3	Cocoa-based spreads, including fillings	7
05.1.4	Cocoa and chocolate products	7
05.1.5	Imitation chocolate, chocolate substitute products	8
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	5
05.2.1	Hard candy	2
05.2.2	Soft candy	2
05.2.3	Nougats and marzipans	2
05.3	Chewing gum	7
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	7
06.3	Breakfast cereals, including rolled oats	5
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	6
07.1	Bread and ordinary bakery wares	4
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	2
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	1
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	1
09.2.4.1	Cooked fish and fish products	1
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	1
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	1
10.4	Egg-based desserts (e.g., custard)	5
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1
12.2	Herbs, spices, seasonings and condiments (e.g., seasoning for instant noodles)	2
12.2.1	Herbs and spices	1
12.2.2	Seasonings and condiments	3



<b>Table 1 - Sweeteners</b>		
<b>Food Category</b>	<b>Food Category Description</b>	<b>Number of Sweeteners (out of 8) with Adopted (Step 8) Provisions that Contain Note 161</b>
12.3	Vinegars	4
12.5	Soups and broths	6
12.6.1	Emulsified sauces (e.g., mayonnaise, salad dressing)	1
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	6
14.1.3.2	Vegetable nectar	6
14.1.3.4	Concentrates for vegetable nectar	5
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	5
14.1.4.1	Carbonated water-based flavoured drinks	1
14.1.4.2	Non-carbonated water-based flavoured drinks, including punches and ades	1
14.1.4.3	Concentrates (liquid or solid) for water-based flavoured drinks	1
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	3
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	1
15.0	Ready-to-eat savouries	1

<b>Table 2 - Colours</b>		
<b>Food Category</b>	<b>Food Category Name</b>	<b>Number of Coulores (out of 13) with Adopted (Step 8) Provisions that Contain Note 161</b>
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	2
01.6.1	Unripened cheese	2
01.6.4	Processed cheese	1
01.6.5	Cheese analogues	1
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	3
02.1.3	Lard, tallow, fish oil, and other animal fats	2
02.2.2	Fat spreads, dairy fat spreads and blended spreads	1
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	2
02.4	Fat-based desserts excluding dairy-based dessert products of food category 01.7	1
04.1.2.3	Fruit in vinegar, oil, or brine	1
04.1.2.4	Canned or bottled (pasteurized) fruit	3
04.1.2.5	Jams, jellies, marmelades	7
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	6
04.1.2.7	Candied fruit	6
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	7
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	6

<b>Table 2 - Colours</b>		
<b>Food Category</b>	<b>Food Category Name</b>	<b>Number of Colours (out of 13) with Adopted (Step 8) Provisions that Contain Note 161</b>
04.1.2.10	Fermented fruit products	1
04.1.2.11	Fruit fillings for pastries	6
04.2.1.2	Surface-treated fresh vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	1
04.2.2	Processed vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	1
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	2
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	5
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	4
04.2.2.5	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed purees and spreads (e.g., peanut butter)	1
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	5
04.2.2.7	Fermented vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products of food categories 06.8.6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	6
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	1
05.1.2	Cocoa mixes (syrups)	1
05.1.3	Cocoa-based spreads, including fillings	4
05.1.5	Imitation chocolate, chocolate substitute products	1
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4	2
05.3	Chewing gum	1
06.3	Breakfast cereals, including rolled oats	1
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	1
07.0	Bakery wares	1
07.1	Bread and ordinary bakery wares	1
07.1.2	Crackers, excluding sweet crackers	3
07.1.3	Other ordinary bakery products (e.g., bagels, pita, English muffins)	3
07.1.4	Bread-type products, including bread stuffing and bread crumbs	2
07.1.5	Steamed breads and buns	1
07.1.6	Mixes for bread and ordinary bakery wares	1
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	4

<b>Table 2 - Colours</b>		
<b>Food Category</b>	<b>Food Category Name</b>	<b>Number of Couloors (out of 13) with Adopted (Step 8) Provisions that Contain Note 161</b>
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	1
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	1
09.3.4	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	1
10.1	Fresh eggs	1
10.2	Egg products	1
10.4	Egg-based desserts (e.g., custard)	2
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	2
12.5	Soups and broths	1
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	2
15.1	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	1

## Annex 3

**Codex Procedural Manual<sup>9</sup>****“STATEMENTS OF PRINCIPLE CONCERNING THE ROLE OF SCIENCE IN THE CODEX DECISION-MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT”<sup>10</sup>**

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

*Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle<sup>11</sup>*

- When health and safety matters are concerned, the *Statements of Principle Concerning the Role of Science* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* should be followed;
- Other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;
- Consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- Recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;<sup>12</sup>
- Only those other factors which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;
- The consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;
- The feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
- The integration of other legitimate factors in risk management should not create unjustified barriers to trade;<sup>13</sup> particular attention should be given to the impact on developing countries of the inclusion of such other factors.”

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<sup>9</sup> Procedural Manual, 20<sup>th</sup> Ed., pp. 209-210.

<sup>10</sup> Decision of the 21<sup>st</sup> Session of the Commission, 1995.

<sup>11</sup> Decision of the 24<sup>th</sup> Session of the Commission, 2001.

<sup>12</sup> Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level.

<sup>13</sup> According to the WTO principles, and taking into account the particular provisions of the SPS and TBT Agreements.