CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 (b) **CX/FA 12/44/8**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-fourth Session

Hangzhou, China 12-16 March 2012

COMMENTS AND INFORMATION ON SEVERAL FOOD ADDITIVES (REPLIES TO CL 2011/4-FA, PART B, POINTS 9, 10 AND 11 AND CL 2011/17-FA)

The following comments have been received from the following Codex members and observers

Brazil, Costa Rica, European Union, Japan, Malaysia, Paraguay, United States of America, CCC, ICGMA, OIV

PART A - REPLY TO CL 2011/4-FA PART B, POINTS 9, 10 AND 11

COSTA RICA

Costa Rica welcomes the opportunity but has not comments on this document.

JAPAN

Japan pleased to provide the following comments in response to CL 2011/4-FA. The following comments are in relation to Part B – Request for Comments and Information point 11.

Point11. Specific additional information on specific provisions for steviol glycosides

Japan would like to provide additional information or proposal in relation to food category 07 and 09.

Food Category No.	Food Category Title	Max Level (mg/kg as steviol equivalent)	Name of the food/Justification
7.1	Bread and ordinary bakery wares and mixes	200	Japan proposes to revise maximum use level with additional information. 1. Name of the foods Breads 2. Justification To add sweetness in combination with sugar To avoid brown discoloration caused by reaction between reducing sugars and amino acids.
7.2	Fine bakery wares (sweet, salty, savoury) and mixes	170	Japan provides following additional information. 1. Name of the foods Doughnuts, Sweet buns 2. Justification To add sweetness in combination with sugar. To avoid brown discoloration caused by reaction between reducing sugars and amino acids.
9.2.4.1	Cooked fish and fish products	240	Japan proposes to revise maximum use level with additional information. 1. Name of the foods (i) Steamed *kamaboko*

Food Category No.	Food Category Title	Max Level (mg/kg as steviol equivalent)	Name of the food/Justification
			(ii) *Tsukudani* 2. Justification for (i) To reduce salty taste in combination with sugar. 3. Justification for (ii) To adjust taste by adding sweetness in combination with sugar. 4. Japan's comments in response to requested info Foods described in name of the foods are neither dried nor dehydrated products.
9.2.4.2	Cooked mollusks, crustaceans, and echinoderms		Japan supports discontinuation of work on proposed draft.
9.2.4.3	Fried fish and fish products, including molluscs, crustaceans, and echinoderms	250	Japan proposes to add a new provision. 1. Name of the foods (i) Fried *kamaboko* (ii) Fried fish product 2. Justification for (i) To reduce salty taste in combination with sugar. 3. Justification for (ii) To reduce salty taste in combination with sugar. To prolong shelf life by moderation of moisture absorption. To avoid brown discoloration caused by reaction between reducing sugars and amino acids. 4. Japan's comments in response to Requested info for (i) During the manufacturing process, salt is used to provide appropriate texture to it. Therefore, we use steviol glycosides in combination of sugar to reduce the salty taste. 5. Japan's comments in response to Requested info for (ii) During the manufacturing process, these fried products are marinated to flavor taste with liquid preparation containing salt and sugar. We use steviol glycosides to reduce salty taste in combination with sugar.
9.2.5	Smoked, dried, fermented and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	100	Japan proposes to add a new provision. 1. Name of the products (i) Dried salted fish product and mollusk (ii) Salted squid gut and salted deep water shrimp (iii) Fermented fish product 2. Justification for (i) To reduce salty taste in combination with sugar. To prolong shelf life by moderation of

Food Category No.	Food Category Title	Max Level (mg/kg as steviol equivalent)	Name of the food/Justification
			moisture absorption. 3. Justification for (ii) and (iii) To reduce salty taste in combination with sugar. 4. Japan's comments in response to Requested info During the manufacturing process, these dried products are marinated to flavor taste with liquid preparation containing salt and sugar. We use Steviol glycosides to reduce salty taste in combination with sugar.
9.3.2	Fish and fish products, including mollusks, crustaceans, and echinoderms, marinated and/or in jelly	120	Japan proposes to add a new provision. 1. Name of the food (i) Vinegar or soy sauce-pickled fish or mollusk (ii) *miso*-pickled fish 2. Justification for (i) To reduce salty or sour taste of the foods in combination with sugar. 3. Justification for (ii) To improve taste by non-fermentative properties of steviol glycosides. To avoid brown discoloration caused by reaction between reducing sugars and amino acids. Note: Foods described in name of the foods are neither dried nor dehydrated products.
9.3.3	Salmon substitutes, caviar, and other fish roe products	120	Japan proposes to add a new provision. 1. Name of the food (i) herring roe (ii) salted cod roe (iii) seasoned cod roe 2. Justification To reduce salty taste in combination with sugar. Note: Foods described in name of the foods are neither dried nor dehydrated products.

EUROPEAN UNION

INS 127 Erythrosine

Erythrosine is allocated a very low numerical ADI of 0.1 mg/kg bw/d by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Therefore, the EU is of the opinion that the use of such colour should be severely restricted. The EU supports only one provision for erythrosine: erythrosine in cocktail cherries and candied cherries at 200 mg/kg. The EU does not support the proposed use level of 300 mg/kg and would like to ask for the explanation why this level is needed and why the level of 200 mg/kg would not be sufficient.

Following the same argumentation the EU does not support the second provision (use of erythrosine in processed comminuted meat, poultry and game with the notes 4 & 16). The EU considers it is much more appropriate to use colours with a higher ADI or ADI "not specified" for these uses.

INS 243 Lauric arginate ethyl ester (LAE)

The EU would like to raise safety concerns about the proposed provisions for lauric arginate ethyl esters. JECFA noted in its evaluation that the JECFA-ADI of 4 mg/kg could be exceeded for high consumers.

The European Food Safety Authority (EFSA) allocated an ADI of 0.5 mg/kg[1] and concluded that this ADI could be significantly exceeded both for children (580%) and adults (100%). EFSA noted the potential effects of LAE on white blood cells on rat strains and concluded that these effects cannot be disregarded. Bearing in mind the potential impact of these findings on the immune system and the exceedance of its ADI, the EU opposes the proposed provisions for LAE.

INS 960 Steviol glycosides

The EU would like to stress that the 69th meeting of the JECFA assigned a low numerical ADI of 4 mg/kg bw and concluded, based on the proposed uses and maximum use levels, that the dietary intake estimates for high consumer children may exceed the ADI. JECFA also concluded that only the proposed "actual intake levels" were likely to be within the ADI".

The EU notes that a wide number of food categories in which the authorisation of steviol glycosides is now requested, were not included in the dietary estimates undertaken by JECFA when it performed its risk assessment. Some of these food categories were already discussed at 43rd CCFA session; others will be discussed at the 44th CCFA session. The EU is of the opinion that the wider range of use for this sweetener may lead to an exceedance of the ADI. The EU would like to get the views of JECFA on this issue. Also, from a procedural point of view, Section II of the Codex Procedural Manual states that any new provisions to be entered into the GSFA should be subject to a JECFA risk assessment, including an intake estimate of the food additive. Therefore, for both safety and procedural reasons, the EU recommends disregarding any request related to the food categories that were not part of the dietary estimates undertaken by JECFA (i.e. REP 11/FA - Appendix VI – FC 08.2; Appendix VII – 04.1.2.1, 04.2.2.1, 05.1.5, 06.4.2, 07.1, 09.2.4.1, 09.2.4.2, 09.2.5, 14.2.1-6.

Finally, the EU considers that, as a general rule, sweeteners should only be authorised in 'energy-reduced' or 'no added sugar' products because otherwise the requirement of Section 3.2 of the GSFA – that the use of additives is justified only when such use has an advantage - would not be fulfilled.

REP 11/FA – Appendix VI

FoodCatNo	Food Category	MaxLevel	Notes	EU comments
05.2	Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4.	700 mg/kg	C & X	
08.2	Processed meat, poultry, and game products in whole pieces or cuts.	80 mg/kg	D & X	Provision not included in the JECFA dietary estimates – therefore should be disregarded. The request is in conflict with the Commodity Standards (096-1981, 097-1981).

Note C For use in microsweets and breath freshening mints at 6000 mg/kg as steviol equivalents.

Note D Except for use in Japanese style 'lachs ham' of pork loin (cured and non-heat-treated) at 120 mg/kg as steviol equivalents.

Note X As steviol equivalents.

REP 11/FA – Appendix VII

FoodCatNo	Food Category	MaxLevel	Notes	EU comments
04.1.2.1	Frozen fruit	40 mg/kg	X & 161	Provision not included in the JECFA dietary estimates – therefore should be disregarded. The request is in conflict with the Commodity Standards on quick frozen fruit (076-1981, 103-1981, 075-1981, 069-1981, 052-1981).
04.2.2.1	Frozen vegetables, seaweeds, and nuts	40 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be

1 Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to an application on the use of ethyl lauroyl arginate as a food additive (Question number EFSA-Q-2006-035 *The EFSA Journal* (2007) 511, 1-27).

FoodCatNo	Food Category	MaxLevel	Notes	EU comments
	and seeds			disregarded. The request is in conflict with the Commodity Standards on quick frozen vegetables (038-1981, 110-1981, 112-1981, 140-1983, 111-1981, 133-1981, 114-1981, 113-1981, 104-1981, 041-1981, 077-1981, 132-1981).
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	350 mg/kg	X	The request is in conflict with the Commodity Standard on Cocoa (Cacao) Mass (Cocoa/Chocolate Liquor) and Cocoa Cake (141-1983).
05.1.2	Cocoa mixes (syrups)	350 mg/kg	X	
05.1.3	Cocoa-based spreads, including fillings	350 mg/kg	X	The request is in conflict with the Commodity Standard on Cocoa Butters (086-1981).
05.1.4	Cocoa and chocolate products	350 mg/kg	X	
05.1.5	Imitation chocolate, chocolate substitute products	350 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	330 mg/kg	X	
06.4.2	Dried pastas and noodles and like products	200 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
07.1	Bread and ordinary bakery wares	50 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	350 mg/kg	X	
09.2.4.1	Cooked fish and fish products	70 mg/kg	H & X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
09.2.4.2	Cooked molluscs, crustaceans, and echinoderms	165 mg/kg	H & X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms	165 mg/kg	H & X	Provision not included in the JECFA dietary estimates – therefore should be disregarded. The request is in conflict with the Commodity Standards (236-2003, 222-2001, 189-1993, 244-2004, 167-1989).
14.2.1	Beer and malt beverages	50 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
14.2.2	Cider and perry	50 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
14.2.3	Grape wines	160 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
14.2.4	Wines (other than	160 mg/kg	X	Provision not included in the JECFA

FoodCatNo	Food Category	MaxLevel	Notes	EU comments
	grape)			dietary estimates – therefore should be disregarded.
14.2.5	Mead	160 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	160 mg/kg	X	Provision not included in the JECFA dietary estimates – therefore should be disregarded.

Notes

Note 161 Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.

Note H For use in dried and dehydrated products only.

Note X As steviol equivalents.

INS 220-228, 539 Sulfites

The EU welcomes the proposal for the reduction of the currently authorised maximum use level (500 mg/kg) in the food category 04.1.2.8 to 300 mg/kg. In light of the CCFA agreement not to consider any proposals for new uses or higher maximum use levels for sulfites due to safety concerns raised by JECFA (ALINORM 10/33/12, paragraph 68), the EU recommends that the use of sulfites within the FC 04.1.2.8 is restricted only to food products in which the use of sulfites is needed. For example, in case of fruit preparations the EU would support the use of sulfites being restricted to rehydrated dried fruit and lychees, mostarda di frutta and in jellying fruit extract, liquid pectin for sale to the final consumer.

PARAGUAY

Paraguay welcomes the opportunity to submit comments in response to CL 2011/4-PR, part B, concerning the order of use and technological justification for use of steviol glycosides in the following food categories:

Appendix VI

01.2 Fermented and renneted milk products (plain)

This food category uses nutritive sweeteners specially to enhance flavours and above all, for people with digestive difficulties to consume these healthy foods it is necessary to add 200 mg/kg, expressed as steviol, to comply with the functions of sweetener, according to provisions (b) and (c) of the GSFA.

01.2.1 Fermented milks (plain)

In the case of natural products, the use of steviol glycosides at levels of 330 mg/kg, expressed as steviol in order to enhance the organoleptic properties (sweetener) allows consumption by people with special dietary needs, pursuant to the requirements (b) and (c) of the GSFA.

04.1.2.2 Dried fruit

This food category uses nutritive sweeteners and we proposed the use of steviol glycosides in levels of 120 mg/kg, expressed as steviol, in accordance with the requirements (b) and (c) of the GSFA. The use level is adquate because in lower levels it does not fulfill the function of sweetener.

Appendix VII

04.1.2.1 Frozen fruit

Technological justification for use

As mass consumption products and their use of nutritive sweeteners, in order to enhance their organoleptic properties (sweeteners), the use of steviol glycosides is proposed in levels of 40 mg/kg, expressed as steviol, according to requirements (b) and (c) of the GSFA.

07.2 Fine bakery wares (sweet, salty, savoury and mixes)

In this product category nutritive sweeteners are used, and considering that steviol glycosides are not degraded at the high temperatures of cooking baked goods, we propose the use of the natural sweetener steviol glycosides in doses of 350 mg/kg, expressed as stevioil according to requirements (b) and (c) of the GSFA.

05.1.4 Cocoa and chocolate products

05.1.3 Cocoa-based spreads, including fillings

For products of mass consumption, mainly by children, which normally use nutritive sweeteners, with the consequent problem of teeth cavities, we propose the use of steviol glycosides in levels of 350 mg/kg, expressed as steviol. The use level is adequate because in lower levels the sweetener function is not fulfilled, according to requirements (b) and (c) of the GSFA.

UNITED STATES OF AMERICA

1. CL 2011/4-FA, Part B, Point 10 - Comments on proposed draft provisions for lauric arginate ethyl ester (LAEE, INS 243) in REP 11/FA, Appendix VI

Background:

Foodstuffs presented for consumption must not contain microorganisms at levels which could cause harm to the final consumers. However foodstuffs are complex organic matrices and consequently can become microbiologically hazardous to the consumer when the principles of hygiene and sanitation are not met, resulting in contamination by pathogens from humans or from the environment during production, processing or preparation, or when they originate from unfit animals, for example, a cow with mastitis or an animal with anthrax.

Due to the wide range of microorganisms potentially present in foods, and in order to assess the microbiological safety of foodstuffs, indicator organisms have been defined whose presence in foods can be used indicate the presence and cause of any contamination. Indicator organisms may be divided into four groups:

1. Plate counts are the most commonly used are aerobic mesophilic counts. A high number usually indicates inadequate processing of food or inadequate transport and storage conditions (e.g. temperature).

2. The presence of enteric bacteria (i.e. coliforms, E.coli) has been widely accepted as an indicator of faecal contamination. Thus, significant numbers of E. coli in a food suggest a general lack of cleanliness in handling and improper storage. The presence of high numbers of Enterobacteriaceae in fresh foods is indicative of poor hygiene in handling and/or inadequate storage. In processed foods when the presence of Enterobacteriaceae or coliforms is high, it suggests that inadequate processing has taken place and/or that a post-process re-contamination caused by a cross-contamination by raw materials, dirty equipment or poor handling has occurred.

3. The presence of staphylococci (i.e. Staphylococcus aureus) is usually indicative of contamination potentially to be found in food products of animal origin or those handled by humans as they are usually found in the skin, mouth or nose of warm-blooded animals (including humans). Inadequately cleaned equipment or raw animal products may also be sources of contamination. High counts also indicate poor hygiene conditions and inadequate temperature control. The presence of mesophilic spore-forming bacteria (e.g. Clostridium botulinum) in canned foods indicates that either the container was not hermetically sealed or that the heat processing was insufficient.

4. Yeasts and moulds could cause food spoilage in those acid foods and foods of low water activity, especially if the products (i.e.: fresh fruit and vegetables, frozen or dried foods) are improperly stored. Additionally, there is also the potential hazard from production of mycotoxins by moulds.

To sum up, the safe consumption of a foodstuff can only be assured by measures undertaken at all steps of the food chain. The responsible use of food preservatives in conjunction sound food handling practices provides a means to inhibit or to reduce the growth of pathogenic microorganisms and those responsible of food spoilage.

LAEE (INS 243)

In the past ten years, a considerable number of trials have been conducted to test the efficacy of LAEE in meat, poultry, fish, and shellfish products. These trials demonstrate that LAEE improves the shelf life of the product and reduces or inhibits the growth of pathogenic microorganisms and also that of indigenous spoilage micro flora of the food.

The USA offers comments and data supporting comments in the tables below:

Table 1: Comments on proposed draft provisions for LAEE in food categories in REP 11/FA, Appendix VI

Table 2: New proposals for use of LAEE

Table 3: Efficacy data (study numbers) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish and shellfish products.

Table 1
Comments on proposed draft provisions for use of LAEE in food categories in REP 11/FA, Appendix VI

LAURIC ARGINATE ETHYL ESTER (INS 243)
Functional Class: Preservative

Codex Food Cat. No.	Codex Food Category	Maximum level (mg/kg)	Technological justification	Efficacy study number described in Table 3 of Attachment 1
08.1	Fresh meat, poultry, and game	200	Due to the fact that these foods are highly perishable, the use of preservatives plays a key role in extension of shelf life and in avoiding the growth of microorganisms. The maximum use level requested is 200 mg/kg. LAEE at this dosage has been demonstrated to be very effective and guarantees safety for consumption and at the same time it can reduce the use of, and therefore consumer exposure to, the food preservatives currently approved for this food category.	1.1 LAE in duck livers 1.2.1 LAE in turkey sausages 1.3.1 LAE in fresh chicken breast 2.1 LAE in fresh beef cuts 2.2 LAE in fresh beef 2.3 LAE in ground beef 3.5 LAE on sliced fresh pork loins
08.2.3	Frozen processed meat, poultry and game products in whole pieces or cuts	200	Freezing foods inactivates any microbes (bacteria, yeast and moulds) present in the food. However, once the frozen product is thawed, the inactivated microbes can again become active, multiplying under the right conditions to levels that can lead to foodborne illness. The treatment of meat, poultry and game products with LAEE before they are frozen, guarantees that once the product is thawed the growth of spores and microorganisms responsible for spoiling the product is prevented. The maximum use level requested is 200 mg/kg of LAEE.	
08.3.3	Frozen processed comminuted meat, poultry, and game products	200	Freezing foods inactivates any microbes (bacteria, yeast and moulds) present in the food. However, once the frozen product is thawed, the inactivated microbes can again become active, multiplying under the right conditions to levels that can lead to foodborne illness. The treatment of meat, poultry and game products with LAEE before they are frozen, guarantees that once the product is thawed the growth of spores and microorganisms responsible for spoiling the product is prevented. The maximum use level requested is 200 mg/kg of LAEE.	
09.1	Fresh fish and fish products, including molluscs, crustaceans, and echinoderms	200	LAEE inhibits the microbial spoilage of desalted fish, fish roe products and sturgeon eggs LAEE, up to 200 mg/kg, has been demonstrated to be an effective preservative and guarantees the safety of the product.	4.3 LAE in fresh salmon

Table 1
Comments on proposed draft provisions for use of LAEE in food categories in REP 11/FA, Appendix VI

LAURIC ARGINATE ETHYL ESTER (INS 243)
Functional Class: Preservative

Codex Food Cat. No.	Codex Food Category	Maximum level (mg/kg)	Technological justification	Efficacy study number described in Table 3 of Attachment 1
09.2.1	Frozen fish, fish fillets, and fish products, including molluscs, crustaceans, and echinoderms	200	Treating these products with LAEE before freezing them guarantees that once the product is thawed the growth of spores and microorganisms responsible for spoilage is avoided. Thus, the presence of LAEE in frozen fish and fish products, including molluscs, crustaceans and echinoderms, guarantees the safe consumption of the product. The maximum use level requested is 200 mg/kg of LAEE.	
09.2.2	Frozen battered fish, fish fillets and fish products, including molluscs, crustaceans, and echinoderms	200	Treating these products with LAEE before freezing them guarantees that once the product is thawed the growth of spores and microorganisms responsible for spoilage is avoided. Thus, the presence of LAEE in frozen fish and fish products, including molluscs, crustaceans and echinoderms, guarantees the safe consumption of the product. The maximum use level requested is 200 mg/kg of LAEE.	
09.2.3	Frozen minced and creamed fish products, including molluscs, crustaceans, and echinoderms	200	Treating these products with LAEE before freezing them guarantees that once the product is thawed the growth of spores and microorganisms responsible for spoilage is avoided. Thus, the presence of LAEE in frozen fish and fish products, including molluscs, crustaceans and echinoderms, guarantees the safe consumption of the product. The maximum use level requested is 200 mg/kg of LAEE.	

Table 2 **New proposals for use of LAEE**				
LAURIC ARGINATE ETHYL ESTER (INS 243) **Functional class: Preservative**				
Codex Food Cat. No.	**Codex Food Category**	**Maximum level (mg/kg)**	**Technological justification**	**Efficacy study number document of August 2011**
08.2.1.1	Cured (including salted) non-heat treated processed meat, poultry, and game products in whole pieces or cuts	200		1.2.2 LAE in sliced smoked turkey 1.3.2 LAE in chicken marinade 3.1 LAE on sliced cured ham
08.2.1.2	Cured (including salted) and dried non-heat treated processed meat, poultry, and game products in whole pieces or cuts	200		1.2.2 LAE in sliced smoked turkey
08.2.1.3	Fermented non-heat treated processed meat, poultry, and game products in whole pieces or cuts	200		3.4 LAE on salami
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	200		1.2.3 LAE in sliced roast turkey 1.3.3 LAE in cooked chicken breast 3.2 LAE on cooked ham
08.3.1.1	Cured (including salted) non-heat treated processed comminuted meat, poultry, and game products	200		1.2.1 LAE in turkey sausages 3.4 LAE on salami
08.3.1.2	Cured (including salted) and dried non-heat treated processed comminuted meat, poultry, and game products	200		3.4 LAE on salami
08.3.1.3	Fermented non-heat treated processed comminuted meat, poultry, and game products	200		3.4 LAE on salami
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	200		3.3 LAE in frankfurters
08.4	Edible casings (e.g., sausage casings)	200		1.2.1 LAE in turkey sausages 3.3 Frankfurters

Table 2
New proposals for use of LAEE

LAURIC ARGINATE ETHYL ESTER (INS 243)
Functional class: Preservative

Codex Food Cat. No.	Codex Food Category	Maximum level (mg/kg)	Technological justification	Efficacy study number document of August 2011
09.2.4	Cooked and/or fried fish and fish products, including molluscs, crustaceans, and echinoderms	200		
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms	200		4.2 LAE in dried, salted cod 4.3 LAE in smoked salmon
09.3.1	Fish and fish products, including molluscs, crustaceans, and echinoderms, marinated and/or in jelly	200	The GSFA acknowledges that fish products in this category have a limited shelf lifeand the use of benzoates and para-hydroxybenzoates is provided for by virtue of the provisions in Food Category 09.3. LAE provides an effective alternative to benzoates and para-hydroxybenzoates as a food preservative.	
09.3.2	Fish and fish products, including molluscs, crustaceans and echinoderms, pickled and/or in brine	200	The GSFA provides for the use of benzoates and para-hydroxybenzoates in products in this food category by virtue of the provisions in Food Category 09.3. LAE provides an effective alternative to benzoates and para-hydroxybenzoates as a food preservative	
09.3.3	Salmon substitutes, caviar and other fish roe products	200		4.1 LAE in lumpfish roe
09.3.4	Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms (e.g., fish paste), excluding products of food categories 09.3.1 - 09.3.3	200	The GSFA provides for the use of benzoates and para-hydroxybenzoates in products in this food category by virtue of the provisions in Food Category 09.3. LAE provides an effective alternative to benzoates and para-hydroxybenzoates as a	

Table 2
New proposals for use of LAEE

LAURIC ARGINATE ETHYL ESTER (INS 243)
Functional class: Preservative

Codex Food Cat. No.	Codex Food Category	Maximum level (mg/kg)	Technological justification	Efficacy study number document of August 2011
			food preservative	

Table 3
Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products

Product Type	Efficacy study number	Food Matrix Tested	Microbial Analysis	Duration of Study	Efficacy Results with LAEE	Conclusions
Poultry - duck	1.1	Duck Liver	*L. monocytogenes, E. coli*, aerobic mesophiles and enterobacteria.	30 days	Aerobic mesophile counts were at 6.80 log colonies forming units per gram (log CFU/g) at Day 30 with 40-50 parts per million (ppm) LAEE, 4.20 log CFU/g with 150-200 ppm LAEE and 8.60 log CFU/g without LAEE (control). *Enterobacteria counts were* at <1.00 log CFU/g at Day 30 with 40-50 ppm LAEE, <1.00 log CFU/g with 150-200 ppm LAEE and 4.40 log CFU/g without LAEE (control). No growth of *L. monocytogenes* and *E. coli* was observed in the control and treated samples of livers for the duration of the study (D30).	LAEE reduced presence of microorganisms compared to the control sample, Extension of shelf life beyond the 5 and 12 days in comparison to the control.
Poultry – turkey	1.2.1	Turkey Sausages	*L. monocytogenes* and aerobic mesophiles	90 days	Aerobic mesophile counts were at 4.1g CFU/g at Day 90 with 200 ppm LAEE and .7g CFU/g without LAEE (control). *L. monocytogenes* counts were at 2 (log colonies forming units per gram (CFU/g) at Day 90 with 200 ppm LAEE and 8.3 log CFU/g without LAEE (control).	LAEE reduced the presence of microorganisms compared to the control sample. Extension of the shelf life of the sausages beyond the 30 days in comparison to the control.

Table 3
Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products

Product Type	Efficacy study number	Food Matrix Tested	Microbial Analysis	Duration of Study	Efficacy Results with LAEE	Conclusions
	1.2.2	sliced smoked turkey	*L. monocytogenes* and Aerobic plate counts (APC)	8 weeks at 4º 4 days at 15ºC	APC were at 1. <1 log CFU/g at Day 56 with 200 ppm LAEE and 6.24 log CFU/g without LAEE (control), at 4.4°C. 2. <1.00 log CFU/g at Day 4 with 200 ppmLAEE and 3.11 log CFU/g without LAEE (control), at 15°C. *L. monocytogenes* were at 1. 7.78 (log colonies forming units per gram (CFU/g) at Day 56 with 200 ppm LAEE and 8.40 log CFU/g without LAEE (control), at 4.4°C 2. 3.01 log CFU/g at Day 4 with 200 ppm LAEE and 5.52 log CFU/g without LAEE (control), at 15°C.	At day 0 the treatment of the sliced smoked turkey with LAEE resulted in a significant reduction (i.e.>1.94 log units) of *L. monocytogenes* inoculated onto sliced smoked turkey compared to the controls. *L. monocytogenes* levels were consistently lower on treated than on untreated samples during storage at 4.4° or 15°C. LAEE treatment also inhibited the growth of aerobic plate counts developing on the samples during storage at 4.4°C and thus may have the potential to extend the microbial shelf life of refrigerated sliced smoked turkey.
Poultry-turkey (contd)	1.2.3 (contd)	sliced roast turkey (contd)	*L. monocytogenes* and Aerobic plate counts (APC) (contd)	4.4ºC and 4 days at 15ºC	*L. monocytogenes* were at 1.4.73 (log colonies forming units per gram (CFU/g) at Day 14 with 200 ppm LAEE and 6.23 log CFU/g without LAEE (control), at 4.4°C 2. 7.35 log CFU/g at Day 4 with 200 ppm LAEE and 7.74 log CFU/g without LAEE at 15ºC. APC were at 1. <1 log CFU/g at Day 14 with 200 ppm LAEE and 6.67 log CFU/g without LAEE (control), at 15°C	At day 0, the treatment of the sliced roast turkey with LAEE resulted in a significant reduction (i.e., 1.42 log units) of *L. monocytogenes* inoculated onto sliced roast turkey compared to the controls. LAEE treatment inhibited the growth of APC developing on the samples during storage at 4.4°C and thus may have the potential to extend the microbial shelf life of refrigerated sliced roast turkey.
Poultry-chicken	1.3.1	Fresh chicken breast	*Salmonella spp*, and	2 days at 4.4ºC and 4 days at 15ºC	APC were at 1. 7.80 log CFU/g at Day 12 with 100-200 ppm LAEE and 8.71 log CFU/g without LAEE (control), at 4.4°C. 2. 7.53 log CFU/g at Day 4 with 100-200	At day 0, the treatment with LAEE resulted in a significant reduction (i.e.3.19 log CFU/cm^2) of *Salmonella* inoculated onto the surface of fresh chicken breasts compared to the controls. The LAEE treatment resulted in inhibition of aerobic plate counts developing on the chicken breasts

Table 3
Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products

Product Type	Efficacy study number	Food Matrix Tested	Microbial Analysis	Duration of Study	Efficacy Results with LAEE	Conclusions
					ppm LAEE and 7.56 log CFU/g without LAEE (control), at 15°C. *Salmonella spp* counts were at 1.1.21 (log colonies forming units per gram (CFU/g) at Day 14 with 100-200 ppmLAEE and 4.16 log CFU/g without LAEE (control), at 4.4°C 2. 5.53 log CFU/g at Day 4 with 100-200 ppm LAEE and 6.47 log CFU/g without LAEE (control), at 15°C.	during storage at 4.4°C and thus may have the potential to extend the microbial shelf life of refrigerated fresh chicken breasts.
	1.3.2	Chicken marinade	aerobic mesophiles	27ays	Aerobic mesophile counts were at 3.20 with 100 ppm LAEE and 9.10 log CFU/g without LAEE (control) at 4°C at Day 27 Aerobic mesophile counts were at 1. 4.00 log CFU/g at Day 11 with 200 ppm LAEE and 4.80 log CFU/g without LAEE (control), at 4°C (frozen samples) 2. 2.10 log CFU/g at Day 11 with 200 ppm LAEE and 4.80 log CFU/g without LAEE (control), at 4°C (thawed samples).	The treatment with 100 ppm LAEE + 150 ppm citric acid in the seasoning for chicken demonstrated a large antimicrobial effect against mesophilic bacteria in comparison with the control sample. At day 12, there was a reduction of more than 5 log CFU/g and at day 27 there was still a reduction of approximately 6 log CFU/g versus the control. In addition, the combined treatment with LAEE and citric acid served to increase considerably the shelf life of the marinated chicken and preserved the organoleptic characteristics of the treated samples. The efficacy differed with each of the two treatments. The most improving results
	1.3.3	Cooked chicken breasts	*L. monocytogenes* and aerobic mesophiles.	11 days	*L. monocytogenes* counts were at 1. 4.00 (log colonies forming units per gram (CFU/g) at Day 11 with 200 ppm LAEE and 4.60 log CFU/g without LAEE (control), at 4°C (frozen samples) 2. 2.30 log CFU/g at Day 11 with 200 ppm LAEE and 4.80 log CFU/g without LAEE (control), at 4°C (thawed samples).	corresponded to the treatment of samples with LAEE before inoculation with Listeria (Treatment No. 2).Independent of the treatment regime, the results clearly demonstrate the efficacy of LAE in cooked chicken breast with the shelf life of the product being extended in comparison to control samples in both cases.
Beef	2.1	Fresh beef cuts	*E. coli* and APC	9 days at 4.4°C and 4 days at	APC were at 1. 3.60 log CFU/g at Day 9 with 200 ppm	At day 0 the immersion treatment with LAE resulted in a significant reduction (i.e. 2.34 log CFU/cm^2) of *E. coli* O157:H7 inoculated onto the surface of fresh beef cuts. The

Table 3
Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products

Product Type	Efficacy study number	Food Matrix Tested	Microbial Analysis	Duration of Study	Efficacy Results with LAEE	Conclusions
				15°C	LAEE and 7.07 log CFU/g without LAEE (control), at 4.4°C. 2. 6.81 log CFU/g at Day 4 with 200 ppm of LAEE and 7.23 log CFU/g without LAEE (control), at 15°C. *E. coli* counts were at 1.0.55 (log colonies forming units per gram (CFU/g) at Day 6 with 200 ppm LAEE and 2.24 log CFU/g without LAEE (control), at 4.4°C 2. 5.97 log CFU/g at Day 4 with 200 ppm LAEE and 7.96 log CFU/g without LAEE (control), at 15°C.	treatment with LAE resulted in a substantial inhibition of aerobic plate counts developing on the beef cuts during storage at 4.4°C and thus has the potential to extend the microbial shelf life of refrigerated fresh beef cuts.
	2.2	Fresh beef	*Escherichia coli* O157:H7	10 minutes	*E. coli* O157:H7 counts were at 2.61 (log colonies forming units per gram (CFU/g) at 10 minutes after spraying 100 ppm LAEE and 4.37 log CFU/g without LAEE (control), at 4°C Aerobic mesophile counts were at 7.10 log CFU/g at Day 5 with 200 pm LAEE and 7.80 log CFU/g without LAEE (control), 5 minutes after treatment of samples followed by grinding.	10 minutes after spraying, the level of *Escherichia coli* O157:H7 in the treated sample was reduced by 1.88 logs compared to the level at the time of inoculation. In the control sample the level was reduced by only 0.13 logs over the same time period. Thus, the treatment of LAE in fresh beef shows good antimicrobial activity against the pathogen *Escherichia coli* O157:H7.
	2.3	Ground beef	Coliforms, *E. coli and* aerobic mesophiles	5 days	Coliforms counts were at 5.70 (log colonies forming units per gram (CFU/g) at Day 5 with 200 ppm LAEE and 6.20	The results demonstrate the high efficacy of LAE in ground beef. LAE at 200 ppm in ground beef reduced the total population of mesophilic aerobes and coliforms at days 1 and 5 compared to untreated controls.Surface treatment of the beef
Beef (contd)	2.3 (contd)				log CFU/g without LAEE (control), 5 minutes after treatment of samples followed by grinding. *E. coli* counts were at 2.10 log CFU/g at Day 5with 200 ppm LAEE and 3.30 log	trims with LAE reduced *Escherichia coli* populations in ground beef by more than 1.0 log CFU/g in 5 minutes. Furthermore, the initial 1.0 log reduction was maintained during the following days of analysis (days 1 and 5). The high initial contamination of the ground beef due to the

Table 3
Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products

Product Type	Efficacy study number	Food Matrix Tested	Microbial Analysis	Duration of Study	Efficacy Results with LAEE	Conclusions
					CFU/g without LAEE (control), , 5 minutes after treatment of samples followed by grinding.	presence of mesophilic aerobes and coliforms suggests that the beef trims were strongly contaminated at the time of purchase.
Pork meats	3.1	Sliced cured ham	*L. monocytogenes* and APC	8 weeks at 4.4°C and 4 days at 15°C.	APC were at 1. <1.00 log CFU/g at Day 56 with 200 ppm LAEE and 1.30 log CFU/g without LAEE (control), at 4.4°C. 2. <1.00 log CFU/g at Day 4 with 200 ppm of LAEE and <1.00 log CFU/g without LAEE (control), at 15°C. *L. monocytogenes* counts were at 1.6.29 (log colonies forming units per gram (CFU/g) at Day 28 with 200 ppm LAEE and 7.51 log CFU/g without LAEE (control), at 4.4°C 2. 6.40 log CFU/g at Day 4 with 200 ppm LAEE and 7.47 log CFU/g without LAEE (control), at 15°C.	LAEE treatment of the sliced cured ham resulted in a significant reduction (i.e., 1.62 log units) of *L. monocytogenes* inoculated onto sliced cured ham at day 0 and this was maintained until day 14 at 4.4ºC and at day 2 at 15ºC. LAE treatment also inhibited the growth of aerobic plate counts developing on the samples during storage at4.4°C and thus has the potential to extend the microbial shelf life of refrigerated sliced cured ham.
	3.2	Cooked ham	mesophilic aerobes, enterobacter, lactobacillus and *Listeria monocytogenes*.	35 days at 4°C. 28 days at 10°C 9 days at 20°C.	Aerobic mesophile counts were at 1. 2.00 log CFU/g at Day 35 with 200 ppm LAEE and 4.80 log CFU/g without LAEE (control), at 4°C. 2. 3.00 log CFU/g at Day 28 with 200 ppm of LAEE and 5.20 log CFU/g without LAEE (control), at 10°C. 3. 2.00 log CFU/g at Day 9 with 200 ppm of LAEE and 6.49 log CFU/g without LAEE (control), at 20°C.	The reduced levels of enterobacter found in the treated samples compared to the controls provide some evidence that treatment with LAE inhibits the growth of pathogens. The results also show that LAE is active against the development of the indigenous microflora of cooked ham. A comparison of the results for mesophilic aerobes from control and treated samples at the different temperatures shows that LAE can extend the shelf life of the product. The efficacy
Pork meats (contd)	3.2 (contd)	Cooked ham (contd)	mesophilic aerobes, enterobacter, lactobacillus		Enterobacter were at 1. 1.00 log CFU/g at Day 35 with 200 ppm LAEE and 1.70 log CFU/g without LAEE (control), at 4°C.	results obtained at 20ºC indicate that LAE has the potential to protect the product in the event of a breakdown in the cooling chain.

Table 3
Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products

Product Type	Efficacy study number	Food Matrix Tested	Microbial Analysis	Duration of Study	Efficacy Results with LAEE	Conclusions
			and *Listeria monocytogenes*.		2. 1.00 log CFU/g at Day 9 with 200 ppm of LAEE and 6.10 log CFU/g without LAEE (control), at 20°C. 3. There was no growth of enterobacter at 10°C Lactobacillus counts were at 1. 1.00 log CFU/g at Day 35 with 200 ppm LAEE and 5.30 log CFU/g without LAEE (control), at 4°C. 2. 1.00 log CFU/g at Day 28 with 200 ppm of LAEE and4.80 log CFU/g without LAEE (control), at 10°C.3. <1.00 log CFU/g at Day 9 with 200 ppm of LAEE and 6.10 log CFU/g without LAEE (control), at 20°C. No presence of *Listeria monocytogenes* was found in the control or treated samples at any of the three storage temperatures.	
	3.3	Frankfurters (i. e. fresh pork, spices, salt and cure)	*Listeria monocytogenes* and Aerobic Plate Counts (APC).	28 days at 4.4°C. 4 days at 15°C.	APC were at 1. 6.19 log CFU/g at Day 28 with 200 ppm LAEE and 6.19 log CFU/g without LAEE (control), at 4.4°C. 2. 6.09 log CFU/g at Day 4 with 200 ppm of LAEE and 7.95 log CFU/g without LAEE (control), at 15°C. *L. monocytogenes* counts were at 1. 6.43 log CFU/g at Day 28 with 200 ppm LAEE and 7.98 log CFU/g without LAEE (control), at 4.4°C. 2. 6.73 log CFU/g at Day 28 with 200 ppm of LAEE and 7.95 log CFU/g without LAEE (control), at 15°C.	At day 0, the treatment with LAE resulted in a significant reduction (i.e., 3.33 log units) of *L. monocytogenes* inoculated onto Frankfurters. The LAE treatment also resulted in an initial reduction and inhibition of aerobic plate counts developing on the Frankfurters during storage at 4.4°C and thus has the potential to extend the microbial shelf life of refrigerated frankfurters.

Table 3
Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products

Product Type	Efficacy study number	Food Matrix Tested	Microbial Analysis	Duration of Study	Efficacy Results with LAEE	Conclusions
					APC were at 1. <1.00 log CFU/g at Day 42 with 200 ppm LAEE and <1.00 log CFU/g without	
	3.4	Sliced salami	*Listeria monocytogenes* and Aerobic Plate Counts (APC).	6 weeks at 4.4°C. 4 days at 15°C.	LAEE (control), at 4.4°C. 2. 2.20 log CFU/g at Day 4 with 200 ppm of LAEE and 1.00 log CFU/g without LAEE (control), at 15°C. *L. monocytogenes* were at 1. 6.64 log CFU/g accounts t Day 42 with 200 ppm LAEE and 8.47 log CFU/g without LAEE (control), at 4.4°C. 2. 5.93 log CFU/g at Day 4 with 200 ppm of LAEE and 8.15 log CFU/g without LAEE (control), at 15°C.	At day 0, the treatment of the inoculated sliced salami with LAE resulted in a significant reduction (i.e., >2.64 log units) in *L. monocytogenes*. In general, the levels of this pathogen were consistently much lower on treated than on untreated samples throughout storage at 4.4°C or 15°C. APC levels were relatively low in all salami samples initially and throughout storage with no evidence of growth on treated or untreated samples at either temperature.
	3.5	Sliced fresh pork loins (contd)	Aerobic mesophiles (contd)	6 days at 4.4°C (contd)	Aerobic mesophile counts were at 1. 3.40 log CFU/g at Day 6 with 200 ppm LAEE and 3.40 log CFU/g without LAEE (control), at 4.4°C.	The results obtained demonstrate that LAE has an effective antibacterial activity in fresh pork loin meat. At day 6, there was a difference of at least five and half logarithmic units between the treated and non-treated samples. Thus, the treatment with LAE serves to extend the shelf life of the product and at the same time improves its microbiological quality.
Fish products	4.1	Fish roe products	total viable count, *E. coli* and *St. aureus*	9 days at 30°C	Total viable counts were at 2.01 log CFU/g at Day 9 with 200 ppm LAEE and 7.15 log CFU/g without LAEE (control) at 30 deg C. *Staphylococcus aureus* counts were at <2.00 log CFU/g at Day 9 with 200 ppm LAEE and 6.79 log CFU/g without LAEE (control). *E. coli* counts were at 2.04 log CFU/g at Day 28 with 200 ppm of LAEE and 7.03 log CFU/g without LAEE (control).	A reduction in the total viable count for samples treated with LAE was observed for each of the three days of analysis. Initially, for LAE-treated samples the count of total viable bacteria was 3.18 log CFU/g and on the ninth day was below the limit of detection. Nevertheless, the counts for untreated control samples increased over the nine days of the study, from 3.40 log to 7.15 log CFU/g. For LAE-treated samples, the *St. aureus* counts decreased progressively from 3.33 log CFU/g on day 0 to less than the limit of detection (<2.00 log CFU/g) on day 9. For untreated controls, *St. aureus* counts increased from 3.68 log to 6.79 log CFU/g over the same period. Similarly, the *E. coli* counts for LAE treated samples

Table 3
Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products

Product Type	Efficacy study number	Food Matrix Tested	Microbial Analysis	Duration of Study	Efficacy Results with LAEE	Conclusions
						declined progressively from 3.14 log CFU/g at day 0 to 2.04 log CFU/g on day 9 while the counts for untreated controls increased over the same period. These results demonstrate the antibacterial efficacy of LAE in fish roe at 200 pm .LAEE retarded the
Fish products (contd)	4.2	Dried salted cod	total viable count and and enteric bacteria	11 days at 4°C	Total viable counts were at 1. 5.03 log CFU/g at Day 11 with 188.2 ppm LAEE, at 4.91 log CFU/g with 69.5 ppm LAEE and 7.43 log CFU/g without LAEE (control). There was no growth of enteric bacteria observed in either LAEE-treated or control samples for Days 1-5.	microbiological spoilage of the cod, thereby improving its microbiological characteristics without affecting its organoleptic properties over time.
	4.3	Fresh salmon and smoked salmon	*L. monocytogenes*	11 or 13 days at 4°C 8 or 9 days at 8°C.	*L. monocytogenes* counts in fresh salmon were at 1. 3.80 log CFU/g at Day 11 with 200 ppm LAEE and 4.60 log CFU/g without LAEE (control), at 4°C. 2. 5.10 log CFU/g at Day 8 with 200 ppm of LAEE and 5.90 log CFU/g without LAEE (control), at 8°C. *L. monocytogenes* counts in smoked salmon were at 1. 4.50 log CFU/g at Day 13 with 200 ppm LAEE and 4.70 log CFU/g without LAEE (control), at 4°C.2. 5.60 log CFU/g at Day9 with 200 ppm of LAEE. and 6.40 log CFU/g without LAEE (control), at 8°C	Fresh salmon: The results obtained for fresh salmon at day 1, show a 1 log reduction in samples at 4ºC and a significant killing effect of around a 2 log reduction in samples stored at 8ºC after 24 hours of application compared to controls. Up to day 4 (shelf life expiration date) there was significant improvement in those samples treated with LAE at 4ºC and 8ºC versus control, probably due to the initial reduction of contamination evident at day 1. At the end of the study, although there was some growth of *Listeria monocytogenes* in all the treated samples, the levels of *Listeria monocytogenes* were still better than in the untreated samples. life expiration date), there was a significant Smoked salmon: For smoked salmon at day 1, there was a 0.8 log reduction in treated samples stored at 4ºC and a 1.3 log reduction in those stored at 8ºC compared to untreated samples. Up to day 6, there was a significant improvement of those samples treated with LAEE at 4ºC and

Table 3 **Efficacy data (study numbers referenced in Table 1, Attachment 1) supporting the comments in Tables 1 and 2 for the use of LAEE in meat, poultry, fish, and shellfish Products**						
Product Type	**Efficacy study number**	**Food Matrix Tested**	**Microbial Analysis**	**Duration of Study**	**Efficacy Results with LAEE**	**Conclusions**
						8ºC versus control as a consequence of the initial reduction of contamination after application of the product.

2. CL 2011/4-FA, Part B, Point 10 - Comments on proposed draft provisions for steviol glycosides (INS 960) in REP 11/FA, Appendix VI

The USA supports the following proposed draft provisions, and recommends their adoption at Step 5/8:

05.2 (Confectionery, including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4) at 700 mg/kg, with Note C and Note X.

3. CL 2011/4-FA, Part B, Point 11 - Specific additional information on specific provisions for steviol glycosides in Table 1 and Table 2 of the GSFA in REP 11/FA, Appendix VII

The USA provides additional technological information on specific provisions for steviol glycosides for consideration by the CCFA.

Technological information on specific provisions for use of steviol glycosides (INS 960) as a sweetener in Table 1 and Table 2 of the GSFA						
Food Cat No	**Food Category**	**Max Level as Steviol equivalents (mg/kg)**	**Comments and/or Notes***	**Step**	**Requested Info**	**Technological Need**
04.1.2.1	Frozen fruit	40 mg/kg	Note X & Note 161	3	Request information on technological need for use of steviol glycosides in this food category specifically, and the use of high intensity sweeteners in this food category in general	During freezing of fruits, some cell walls break, leaching out water that affects the taste of frozen fruits. Intense sweeteners provide sweetness to that water and make the frozen fruit more palatable. Steviol glycosides provide a no calorie alternative, especially for those who desire a natural sweetener.
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts	40 mg/kg	Note X	3	Request information on technological need for use of steviol glycosides in this food category specifically, and the use of high intensity sweeteners in this food category in general	Intense sweeteners modulate the specific vegetable flavor note to make the frozen vegetables taste better. They also add a slight sweetness to make frozen vegetable more palatable. Steviol glycosides provide a no calorie alternative, especially for those who desire a natural sweetener.
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	800 mg/kg	Note X	3	Request information on technological need and	Products containing Steviol glycoside are currently in global commerce. For no sugar added

Technological information on specific provisions for use of steviol glycosides (INS 960) as a sweetener in Table 1 and Table 2 of the GSFA						
Food Cat No	**Food Category**	**Max Level as Steviol equivalents (mg/kg)**	**Comments and/or Notes***	**Step**	**Requested Info**	**Technological Need**
					justification of use level consistent with Section 3.2 of the Preamble	cocoa mix (powder), use level can reach up to 2500 ppm Rebaudioside A in the dry mix. 1. JECFA considered at 1,000 mg/kg Steviol glycoside. 2. Although not among the categories listed as technologically justified for using sweeteners by the 39th CCFA, the Codex Standard for Cocoa Powders (Cocoas) and Dry Mixtures of Cocoa and Sugars (CXS 105-1981, Rev.1-2001) has provisions for sweeteners including aspartame at 3,000 mg/kg. 3. Aspartame at 3,000 mg/kg in GSFA.
05.1.2	Cocoa mixes (syrups)	800 mg/kg	Note X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the	Levels are necessary. Levels are similar to cocoa mix (powder). In a concentrated format, use level of no-sugar added version could.
					Preamble	approach 2500 ppm as Rebaudioside A. 1. JECFA considered at 1,000 mg/kg SG. 2. Technologically justified per 39th CCFA. 3. Aspartame at 1,000 mg/kg in GSFA
05.1.3	Cocoa-based spreads, including fillings	350 mg/kg	Note X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Stevia glycosides provide the sweetness without calories that subdues the peak bitterness of cocoa and enhances and round out flavor
05.1.4	Cocoa and chocolate products	350 mg/kg	Note X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Levels of 350 mg/kg steviol eq. are necessary. 1. JECFA considered at 2,000 mg/kg SG. 2. Technologically justified per 39th CCFA. 3. Aspartame at 3,000 mg/kg in GSFA.
05.2	Confectionery, including hard and soft candy, nougats, etc., other than food categories 05.1, 05.3	700 mg/kg	Note C, Note X		Request information on technological need and justification of use level consistent with Section 3.2 of	Necessary and used in sugar-free candies. 1. JECFA considered at: - 1,000 mg/kg SG for the broader 5.2 category - 6,000 mg/kg SG for "breath freshening

Technological information on specific provisions for use of steviol glycosides (INS 960) as a sweetener in Table 1 and Table 2 of the GSFA						
Food Cat No	**Food Category**	**Max Level as Steviol equivalents (mg/kg)**	**Comments and/or Notes***	**Step**	**Requested Info**	**Technological Need**
	and 05.4				the Preamble	microsweets" - 2,000 mg/kg SG for "strongly flavored throat pastilles with no added sugar." 2. Technologically justified per 39th CCFA. 3. Aspartame at 3,000 mg/kg in GSFA.
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	330 mg/kg	Note X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Steviol glycosides reduce the calories (sugar) and enhance flavor, especially for consumers that desire a natural sweetener.
06.4.2	Dried pastas and noodles and like products	200 mg/kg	Note X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Stevia glycosides moderate the bitter taste of gluten that is generally added in some products. It also adds a slight sweetness to round out the taste profile.
07.1	Bread and ordinary bakery wares	50 mg/kg	Note X	3	Request explanation of technological need for the use of a sweetener in this food category.	Stevia glycosides moderate the bitter taste of gluten that is generally added to some products. It also adds a slight sweetness to round out the taste profile.
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	350 mg/kg	Note X	3	Request explanation of technological need for the use of a sweetener in this food category.	Stevia glycosides moderate the bitter taste of gluten that is generally added to some products. It also adds a slight sweetness to round out the taste profile.
						Levels of 350 mg/kg steviol eq. are necessary and used in a variety of reduced sugar bakery. SGs are stable through the baking process, therefore less is required as compared to aspartame. (e.g., cakes; cookies; French toast, pancakes, waffles; muffins, scones, doughnuts; pastries, pie crust; sweet breads, rolls) 1. JECFA considered at 1,700 mg/kg SG. 2. Technologically justified per 39th CCFA. 3. Aspartame at 1,700 mg/kg in GSFA.
09.2.4.1	Cooked fish and fish products	70 mg/kg	Note H & Note X	3	Request information on use in dried and dehydrated	Stevia glycosides moderate the taste and flavor profile and are sometimes used to round out the

Technological information on specific provisions for use of steviol glycosides (INS 960) as a sweetener in Table 1 and Table 2 of the GSFA						
Food Cat No	**Food Category**	**Max Level as Steviol equivalents (mg/kg)**	**Comments and/or Notes***	**Step**	**Requested Info**	**Technological Need**
					products, specifically use in seafood from the sea versus fresh water.	low level fishy (oxidative) note.
09.2.4.2	Cooked mollusks, crustaceans, and echinoderms	165 mg/kg	Note H & Note X	3	Request information on use in dried and dehydrated products, specifically use in seafood from the sea versus fresh water.	Moderates the taste and flavor profile. Stevia glycosides are sometimes used to round out the low level fishy (oxidative) note.
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans and echinoderms	165 mg/kg	Note H & Note X	3	Request information on use in dried and dehydrated products, specifically use in seafood from the sea versus fresh water.	Steviol glycosides moderate the taste and flavor profile by adding a light sweetness, which also helps in modulating and rounding out the smoky and/or fermentation flavor notes.
14.2.1	Beer and malt beverages (contd)	50 mg/kg	Note X	3	Request information on technological need	Steviol glycosides round out the bitterness and grassy flavor note from malt. Reduces the need for added glucose for balancing the taste profile.
14.2.2	Cider and perry	50 mg/kg	Note X	3	Request information on technological need	Steviol glycosides enhance the sweetness and cider flavor profile.
14.2.3	Grape wines	160 mg/kg	Note X	3	Request information on technological need	Steviol glycosides add some sweetness and enhance the grape flavor without the addition of calories.
14.2.4	Wines (other than grape)	160 mg/kg	Note X	3	Request information on technological need	Steviol glycosides add light sweetness and enhance the flavor without the addition of calories.
1.4.2.5	Mead	160 mg/kg	Note X	3	Request information on technological need	Steviol glycosides add light sweetness and enhance the flavor without the addition of calories.
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	160 mg/kg	Note X	3	Request information on technological need	
NOTES						
Note 161	Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble					
Note H	For use in dried and dehydrated products only					

Technological information on specific provisions for use of steviol glycosides (INS 960) as a sweetener in Table 1 and Table 2 of the GSFA						
Food Cat No	**Food Category**	**Max Level as Steviol equivalents (mg/kg)**	**Comments and/or Notes***	**Step**	**Requested Info**	**Technological Need**
Note X	As steviol equivalents					
Note C	For use in microsweets and breath freshening mints at 6000 mg/kg as steviol equivalents					

CCC (CALORIE CONTROL COUNCIL)

The Calorie Control Council (CCC) is a non-government organization (NGO) representing companies that make low calorie and reduced fat foods and beverages, including companies that make sweeteners and fat replacers used in these products.

The CCC is herein providing comments, specifically on steviol glycosides, in response to:

1) CL 2011/4-FA PART B, Point 10: Comments at Step 6 and 3 on several draft and proposed draft provisions for erythrosine (INS 127); lauric arginate ethyl ester (INS 243); steviol glycosides (INS 960); sulfites (INS 220-228, 539) in Table 1 and Table 2 of the GSFA (para. 75 and Appendix VI)

2) CL 2011/4-FA PART B, Point 11: Specific additional information on specific provisions for steviol glycosides (INS 960)) in Table 1 and Table 2 of the GSFA (para 76 and Appendix VII)

The CCC supports the proposed maximum levels of use at Step 3 for steviol glycosides in the following categories from CL 2011/4-FA Part B, Point 10:

05.2 Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4 at 700 mg/kg, with footnotes C (for use in microsweets and breath freshening mints at 6000 mg/kg as steviol equivalents) and X (as steviol equivalents).

08.2 Processed meat, poultry, and game products in whole pieces or cuts at 80 mg/kg with footnotes D [except for use in Japanese style 'lachs ham' of pork loin (cured and non-heat-treated) at 120 mg/kg as steviol equivalents].

Technological need and justification has previously been provided for the use of steviol glycosides in categories 05.2 and 08.2 as described above and the 34th CCFA developed a list food Categories in which the use of sweeteners is technologically justified, including category 5.1.

Specific additional information on specific provisions for steviol glycosides as requested in CL 2011/4-FA, Part B, Point 11, is provided in the table below:

(for further information)

Steviol Glycosides

Ins 960 Steviol Glycosides Functional Class: Sweetener

Food Cat No	Food Category	Max Level	Comments	Step	Requested Info	Technological Need
04.1.2.1	Frozen fruit	40 mg/kg	X & 161	3	Request information on technological need for use of steviol glycosides in this food category specifically, and the use of high intensity sweeteners in this food category in general	During freezing of fruits, some cell walls break, leaching out water that affects the taste of frozen fruits. Intense sweeteners provide sweetness to that water and make the frozen fruit more palatable. Steviol glycosides provide a no calorie alternative, especially for those who desire a natural sweetener.
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera),	40 mg/kg	X	3	Request information on technological need for use of steviol glycosides in this food category specifically, and the use of high	Intense sweeteners modulate the specific vegetable flavor note to make the frozen vegetables taste better. They also add a slight

Food Cat No	Food Category	Max Level	Comments	Step	Requested Info	Technological Need
	seaweeds, and nuts and				intensity sweeteners in this food category in general	sweetness to make frozen vegetable more palatable. Steviol glycosides provide a no calorie alternative, especially for those who desire a natural sweetener.
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	350 mg/kg	X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Stevia glycosides provide the sweetness without calories that subdues the peak bitterness of cocoa and enhances and rounds out the cocoa flavor.
05.1.2	Cocoa mixes (syrups)	350 mg/kg	X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Stevia glycosides provide the sweetness without calories that subdues the peak bitterness of cocoa and enhances and rounds out the cocoa flavor.
05.1.3	Cocoa-based spreads, including fillings	350 mg/kg	X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Stevia glycosides provide the sweetness without calories that subdues the peak bitterness of cocoa and enhances and round out the cocoa flavor.
05.1.4	Cocoa and chocolate products	350 mg/kg	X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Stevia glycosides provide the sweetness without calories that subdues the peak bitterness of cocoa and enhances and rounds out the cocoa flavor.
05.1.5	Imitation chocolate, chocolate substitute products	350 mg/kg	X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Stevia glycosides provide the sweetness without calories that subdues the peak bitterness of cocoa and enhances and rounds out the cocoa flavor.
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet	330 mg/kg	X	3	Request information on technological need and justification of use level consistent	Steviol glycosides reduce the calories (sugar) and enhance flavor, especially for

Food Cat No	Food Category	Max Level	Comments	Step	Requested Info	Technological Need
	sauces				with Section 3.2 of the Preamble	consumers that desire a natural sweetener.
06.4.2	Dried pastas and noodles and like products	200 mg/kg	X	3	Request information on technological need and justification of use level consistent with Section 3.2 of the Preamble	Stevia glycosides moderate the bitter taste of gluten that is generally added in some products. It also adds a slight sweetness to round out the taste profile.
07.1	Bread and ordinary bakery wares	50 mg/kg	X	3	Request explanation of technological need for the use of a sweetener in this food category.	Stevia glycosides moderate the bitter taste of gluten that is generally added to some products. It also adds a slight sweetness to round out the taste profile.
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	350 mg/kg	X	3	Request explanation of technological need for the use of a sweetener in this food category.	Stevia glycosides moderate the bitter taste of gluten that is generally added to some products. It also adds a slight sweetness to round out the taste profile.
09.2.4.1	Cooked fish and fish products	70 mg/kg	H & X	3	Request information on use in dried and dehydrated products, specifically use in seafood from the sea versus fresh water.	Stevia glycosides moderate the taste and flavor profile and are sometimes used to round out the low level fishy (oxidative) note.
09.2.4.2	Cooked mollusks, crustaceans, and echinoderms	165 mg/kg	H & X	3	Request information on use in dried and dehydrated products, specifically use in seafood from the sea versus fresh water.	Moderates the taste and flavor profile. Stevia glycosides are sometimes used to round out the low level fishy (oxidative) note.
09.2.5	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans and echinoderms	165 mg/kg	H & X	3	Request information on use in dried and dehydrated products, specifically use in seafood from the sea versus fresh water.	Steviol glycosides moderate the taste and flavor profile by adding a light sweetness, which also helps in modulating and rounding out the smoky and/or fermentation flavor notes.

Food Cat No	Food Category	Max Level	Comments	Step	Requested Info	Technological Need
14.2.1	Beer and malt beverages	50 mg/kg	X	3	Request information on technological need	Steviol glycosides round out the bitterness and grassy flavor note from malt. Reduces the need for added glucose for balancing the taste profile.
14.2.2	Cider and perry	50 mg/kg	X	3	Request information on technological need	Steviol glycosides enhance the sweetness and cider flavor profile.
14.2.3	Grape wines	160 mg/kg	X	3	Request information on technological need	Steviol glycosides add some sweetness and enhance the grape flavor without the addition of calories.
1.4.2.4	Wines (other than grape)	160 mg/kg	X	3	Request information on technological need	Steviol glycosides add light sweetness and enhance the flavor without the addition of calories.
1.4.2.5	Mead	160 mg/kg	X	3	Request information on technological need	Steviol glycosides add light sweetness and enhance the flavor without the addition of calories.
14.2.6	Distilled spirituous beverages containing more than 15% alcohol	160 mg/kg	X	3	Request information on technological need	Steviol glycosides moderate the initial pungent note and add a slight sweetness that suppresses the bitterness and rounds out the taste profile.
Notes						
Note 16	Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble					
Note H	For use in dried and dehydrated products only					
Note X	As steviol equivalents					

CCC appreciates consideration of its comments provided above.

ICGMA

The International Council of Grocery Manufacturers Associations (ICGMA) is a nongovernmental organization that represents foods and consumer packaged goods manufacturers globally. ICGMA promotes the harmonization of food standards and policies based on science and is a strong supporter of Codex Alimentarius. ICGMA also works to facilitate international trade of food products by eliminating or preventing artificial barriers to trade and believes that global harmonization of food additive standards is important to achieve that goal.

ICGMA is pleased to provide the following comments in response to:

- CL 2011/4-FA PART B Point 10: Comments at Step 6 and 3 on several draft and proposed draft provisions for … steviol glycosides (INS 960) in Table 1 and Table 2 of the GSFA (para. 75 and Appendix VI)[2]; AND
- CL 2011/4-FA PART B Point 11: Specific additional information on specific provisions for steviol glycosides (INS 960)) in Table 1 and Table 2 of the GSFA (para. 76 and Appendix VII);

ICGMA provided in-depth technical comments at the last CCFA session regarding Steviol Glycoside provisions during the electronic Working Group and the physical Working Group on the GSFA. In most cases, justification was provided on the basis of technological need as it relates to sweetness equivalency to aspartame AND:

Food use levels proposed to JECFA as reported in WHO FAS 60 Report[3];

(i) Food categories in which the use of sweeteners is technologically justified[4]; and/or

(ii) Existing provisions in the GSFA for other sweeteners[5].

STEVIOL GLYCOSIDES (4 mg/kg bw as steviol equivalents) Synonyms: Stevioside, Rebaudioside A, Stevia Extract INS: 960				
Function: sweetener				
FoodCatNo	Food Category	ML as Steviol Glicosides (mg/kg)	Notes	ML (mg/kg) as stev eq.
05.2[6]	Confectionery, including hard and soft candy, nougats, etc., other than food categories 05.1, 05.3 and 05.4	6,000 mg/kg	Note C - For use in microsweets and breath freshening mints at 6000 mg/kg as steviol equivalents. Note X – As steviol equivalents.	**Levels of 700 mg/kg steviol eq. are necessary and used in sugar-free candies.** 1. JECFA considered at: - 1,000 mg/kg SG for the broader 5.2 category - 6,000 mg/kg SG for "breath freshening microsweets" - 2,000 mg/kg SG for "strongly flavored throat pastilles with no added sugar." 2. Technologically justified per 39th CCFA. 3. Aspartame at 3,000 mg/kg in GSFA.
05.1.1[7]	Cocoa mixes (powders) and cocoa mass/cake	2,500 mg/kg	Note X – As steviol equivalents.	**Levels of 800 mg/kg steviol eq. are necessary. Products containing SG are currently in global commerce. For no sugar added cocoa mix (powder), use level can reach up to 2500 ppm Rebaudioside A in the dry mix.** 1. JECFA considered at 1,000 mg/kg SG. 2. Although not among the categories listed as technologically justified for using sweeteners by the 39th CCFA, the Codex Standard for Cocoa Powders (Cocoas) and Dry Mixtures of Cocoa and Sugars (CXS 105-1981, Rev.1-2001) has provisions for sweeteners including aspartame at 3,000 mg/kg. 3. Aspartame at 3,000 mg/kg in GSFA.
05.1.2	Cocoa mixes (syrups):	2,500 mg/kg	Note X – As steviol	**Levels of 800 mg/kg steviol eq. are necessary. Levels are similar to cocoa**

[2] REP11/FA – www.codexalimentarius.net/download/report/759/REP11_FAe.pdf.
[3] WHO Food Additive Series (FAS) 60 Report Tables 3&4, pp. 205-207 -http://whqlibdoc.who.int/publications/2009/9789241660600_eng.pdf
[4] CCFA developed a list of Codex food Categories in which the use of sweeteners is technologically justified at its 39th session – CRD Appendix V.
[5] Codex General Standard for Food Additives - http://www.codexalimentarius.net/gsfaonline/docs/CXS_192e.pdf.
[6] REP 11/FA - Appendix VI pp. 62-63 (Steviol provision 5.2.)
[7] REP 11/FA - Appendix VII pp. 64-65 (Steviol provisions 5.1.1., 5.1.2., 5.1.3., 5.1.4., 5.1.5., 5.4., 7.2.)

			equivalents.	**mix (powder). In a concentrated format, use level of no-sugar added version could approach 2500 ppm as Rebaudioside A.** 1. JECFA considered at 1,000 mg/kg SG. 2. Technologically justified per 39th CCFA. 3. Aspartame at 1,000 mg/kg in GSFA.
05.1.4	Cocoa and chocolate products	2,000 mg/kg	Note X – As steviol equivalents.	**Levels of 350 mg/kg steviol eq. are necessary.** 1. JECFA considered at 2,000 mg/kg SG. 2. Technologically justified per 39th CCFA. 3. Aspartame at 3,000 mg/kg in GSFA.
7.2	Fine bakery wares (sweet, salty, savoury) and mixes [For all of – 07.2.1 Cakes, cookies and pies (e.g., fruit-filled or custard types) 07.2.2 Other fine bakery products (e.g., doughnuts, sweet rolls, scones, and muffins) 07.2.3 Mixes for fine bakery wares (e.g., cakes, pancakes)]	1,000 mg/kg	Note X – As steviol equivalents.	**Levels of 350 mg/kg steviol eq. are necessary and used in a variety of reduced sugar bakery.** SGs are stable through the baking process, therefore less is required as compared to aspartame. (e.g., cakes; cookies; French toast, pancakes, waffles; muffins, scones, doughnuts; pastries, pie crust; sweet breads, rolls) 1. JECFA considered at 1,700 mg/kg SG. 2. Technologically justified per 39th CCFA. 3. Aspartame at 1,700 mg/kg in GSFA.

OIV (INTERNATIONAL ORGANISATION OF VINE AND WINE)

The OIV would like to provide specific comments and information, on Part B of the Circular Letter CL 2011/4-FA and more particularly on the point 11 "Specific additional information on specific provisions for steviol glucosides (INS No 960) in table 1 and table 2 of the GSFA concerning the Food category 14.2.3 grape wines. (Appendix VII of the REP11/FA)

The 43rd Session of the Codex Committee on Food Additives (CCFA) considered the recommendations of the physical Working Group (pWG) on the General Standard for Food Additives (GSFA). The Committee endorsed the recommendations of the p-WG regarding the requests for specific information on the proposed draft provisions for steviol glycosides and circulation for comments at Step 3 and 6 of the draft and proposed draft provisions for erythrosine, lauric arginate ethyl ester, steviol glycosides and sulfites. It was noted that the proposed draft provisions for steviol glycosides would be discontinued if the requested specific information was not provided at the next session of the Committee.

The Committee agreed to request specific additional information on the food additives listed in Appendix VII and reminded Members and Observers that, when submitting information, they needed to comply with the Procedures for consideration of entry and review of food additive provisions in the General standard for food additives, included in the Procedural Manual, in particular concerning the justification for the use and technological need.

Steviol glucosides

INS No 960

Functionnal class: Sweetener

The OIV has not recognized the use of Steviol Glucosides in the wine making process.

The OIV considers that sweetening is very well regulated in the wine making process and no sweeteners, as additive, are used for grape wines (category 14.2.3 and sub categories).

In different regulations, sweetening of wine may be authorised only if carried out using one or more of the following products : (a) grape must; (b) concentrated grape must; (c) rectified concentrated grape must. For example, It is the case for the European regulation COMMISSION REGULATION (EC) No 606/2009 of 10 July 2009 (Annex 1 D)

The use of Steviol glucosides could be considered and evaluated in other food categories like Category 14.2.4 Wines other than grapes or 14.2.7 Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)

Therefore, the OIV is not in a position to support that the 44th CCFA recommend to adopt the provision of Steviol glucosides for Grape wines (category 14.2.3.).

PART B - REPLY TO CL 2011/17-FA

BRAZIL

Provision for beta carotenes in food category 02.1.2 "Vegetable oils and fats" as presented in Appendix IV of REP11/FA

The Standard for Edible Fats and Oils Not Covered by Individual Standards (CODEX STAN 19-1981) applies to oils and fats and mixtures thereof in a state for human consumption. It includes oils and fats that have been subjected to processes of modification (such as trans-esterification or hydrogenation) or fractionation.

This Standard does not apply to any oil or fat which is covered by one of the following:

the Codex Standard for Named Animal Fats;

the Codex Standard for Named Vegetable Oils;

the Codex Standard for Olive Oils and Olive-pomace Oils.

According to item 3.2-Colours: "No colours are permitted in vegetable oils covered by this Standard… colours are permitted for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, as long as the added colour does not deceive or mislead the consumer by concealing damage or inferiority or by making the product appear to be of greater than actual value".

Brazil understands that colours are justified only for oils and fats that have been subjected to processes of modification (such as trans-esterification or hydrogenation) or fractionation, which lose colour in processing. That is the case of vanaspati, mentioned by Malaysia. Brazil does not agree with the use in other vegetable fats and oils, since it would not be possible to distinguish the intention of standardizing colour to making the product appear to be of greater that actual value. Furthermore, any use of colours in vegetable fats and oils would mislead the consumer of the products' real quality.

COSTA RICA

Costa Rica has not comments regarding this document and considers the draft document to be well prepared.

MALAYSIA

Draft Provision for Carotenoids in Food Category 02.1.2 "Vegetable Oils and Fats" of the GSFA

Malaysia kindly recalls that the draft provision on the use of carotenoids in food category 02.1.2 Vegetable oils and fats at 1000 mg/kg had been discussed since 2007 and the proposed maximum level was amended to 250 mg/kg and was recommended for adoption by the eWG for the 40th CCFA in 2008. However, due to time constraint, this draft provision was deferred until the 43rd CCFA. Malaysia was one of the countries who supported the use besides Japan, Korea and Singapore as indicated in the discussion paper CX/FA 11/43/7 for the 43rd CCFA. However, the draft provision was proposed to be discontinued by the Physical WG on the GSFA at the 43rd CCFA which was subsequently agreed by the 43rd CCFA and forwarded for discontinuation to the 34th CAC.

Malaysia notes that the 34th CAC approved discontinuation of work on all draft and proposed draft food additive provisions of the GSFA, as proposed by the 43rd CCFA, with the exception of the draft provision for carotenoids in food category 02.1.2 "Vegetable oils and fats", which was returned to the CCFA for further consideration, based on comments from Malaysia.

In this regard, Malaysia wishes to inform the Committee that carotenoids are added into products such as vanaspati that falls under the category of 2.1.2. It is added to restore natural colour lost during deodorization of vegetable oil used in the manufacture of the product.

In addition, Malaysia notes that Codex Standard for Edible Fats and Oils Not Covered by Individual Standards, CODEX STAN 19-1981 permits the addition of certain colour, including individual carotenoid for the purpose of restoring natural colour lost in processing or for the purpose of standardizing colour, as long as the added colour does not deceive or mislead the consumer by concealing damage or inferiority or by making the product appear to be of greater than actual value.

As such, Malaysia is strongly of the opinion that the use of carotenoids in food category 2.1.2 is justified. Therefore, Malaysia would like to propose the adoption of draft provision of carotenoids in food category 2.1.2 at 250 mg/kg at the next CAC at Step 8.

UNITED STATES OF AMERICA

Comment on the Draft Provision for Carotenoids (INS 160a(i), 160a(iii), 160e, 160f) in food category 02.1.2 (Vegetable oils and fats) of the GSFA

The United States offers the following comments with regard to the further consideration of the draft provision for carotenoids (β-carotenes (synthetic) (INS 160a(i)); β-carotenes (*Blakeslea trispora*) (INS 160a(iii)); β-apo-8'-carotenal (INS 160e); and carotenoic acid, ethyl ester, β-apo-8'- (INS 160f)) in food category 02.1.2 (Vegetable oils and fats) at a maximum level of 1000 mg/kg.

The United States permits the use of carotenoids as follows:

- β-apo-8'-carotenal (INS 160e) is used to color foods in general, at a level not to exceed 15 mg/pound of solid or semisolid food, or 15 mg/pint of liquid food, which is equivalent to approximately 33 mg/kg of solid, semisolid or liquid food.
- Synthetic β-carotene (INS 160a(i)) and β-carotene from natural sources (which would include β-carotenes (*Blakeslea trispora*) (INS 160a(iii)) are used to color foods in general in accordance with good manufacturing practices (GMP).
- β-apo-8'-carotenal, synthetic β-carotene, and β-carotene from natural sources may not be used to color foods for which standards of identity have been established.
- Synthetic β-carotene is also permitted for use as a nutrient supplement in dairy product analogs, fats and oils, processed fruits and fruit juices in accordance with GMP, and as a source of vitamin A in infant formula. The United States notes however, that the use of carotenoids as a nutrient are not included in the GSFA.

The United States also notes that the *Codex Standard for Edible Fats and Oils Not Covered by Individual Standards* (CODEX STAN 19-1981) includes a provision for the use of carotenoids (INS 160a(i), INS 160a(iii), INS 160e, and INS 160f) at a level of 25 mg/kg, singly or in combination, for the purpose of restoring the natural color lost in processing or for standardizing the color, provided that the added color does not deceive or mislead the consumer by concealing damage or inferiority, or by making the product appear to be of greater than actual value.

Based on this information, the United States supports a provision for the use of carotenoids (INS 160a(i), 160a(iii), 160e and 160f) in food category 02.1.2 at a maximum use level of 35 mg/kg with a Note "Singly or in combination, for the purpose of restoring the natural color lost in processing or for standardizing the color, provided that the added color does not deceive or mislead the consumer by concealing damage or inferiority, or by making the product appear to be of greater than actual value." This provision takes into account the provision for carotenoids in the *Codex Standard for Edible Fats and Oils Not Covered by Individual Standards*.