CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 5(f) **CX/FA 13/45/12**

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PROPOSALS FOR NEW ADDITIVE PROVISIONS AND/OR REVISION OF FOOD ADDITIVE PROVISIONS OF THE GSFA

(Replies to CL 2012/5-FA, Part B, point 10)

BACKGROUND

1. The 44th Session of the Codex Committee on Food Additives (CCFA) discussed the need to establish a process for consideration of unsolicited proposals for new or revised entries in the GSFA. The Committee recalled that the *Procedure for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives* [1] provided detailed information that should be included in support of specific requests for new and revised provisions for the GSFA. The Committee agreed to issue a Circular Letter requesting proposals for new or revised provisions for the GSFA to be submitted according to the *Procedure*. The Committee also agreed to consider only proposals submitted by the deadline specified in the Circular Letter.[2] The United States of America (USA) was requested to compile, in a structured form, the new or revised provisions for the GSFA.[3] The Committee also agreed to establish a physical Working Group, which would meet immediately prior to the 45th Session and be chaired by the USA, working in English only, to consider and prepare recommendations for the Plenary based on the information compiled by the USA.[4]

2. CL 2012/5-FA, Part B, Point 10 requested new or revised provisions for the GSFA. Comments were received from Costa Rica, European Union, New Zealand, USA, Calorie Control Council (CCC), International Chewing Gum Association (ICGA), International Council of Grocery Manufacturers Associations (ICGMA), and International Sweeteners Association (ISA). These comments are organized by food additive and summarized in Appendix 1 to this document. For comments where a detailed technological justification was provided, those comments are summarized in Appendix 1 and the full comment is presented in Appendix 3. In addition to those comments provided in response to CL 2012/5 FA, Appendix 1 also includes the proposal from Brazil contained in CRD 18 (44th CCFA).[5]

3. Although not requested, new proposals for the use of additives currently in Table 3 of the GSFA that have the function “acidity regulator” or “emulsifier, stabilizer, thickener” were submitted to the electronic working group on the GSFA (GSFA eWG).[6] New proposals were received from Brazil, Costa Rica, European Food Emulsifiers Manufacturers Association (EFEMA), ICGMA, International Food Additives Council (IFAC), Marinalg International (Marinalg), and International Organization of the Vine and Wine (OIV). These proposals are organized by food additive and summarized in Appendix 2.

Editorial comments

4. In their submitted comments to CL 2012/5-FA, Part B, Point 10, New Zealand requested the inclusion of several additives for use in food category 14.2.3 (Grape wines) that do not meet the criteria for inclusion in the GSFA.[7] Therefore, the proposed provisions for the following substances have not been included in Appendix 1, but New Zealand’s comments are included in Appendix 3: calcium tartrate (INS 354), metatartaric acid and yeast mannoproteins. Additionally, tannins (INS 181) are not included because the JECFA evaluation for

[1] Codex Procedural Manual, 20th Ed., pp. 55-61.
[2] REP 12/FA, paras. 86-88.
[3] REP 12/FA, para. 134.
[4] REP 12/FA, para. 135.
[5] REP 12/FA, para. 87.
[6] REP 12/FA, paras. 94-98.
[7] For an additive to be included in the GSFA, it must have been assigned an Acceptable Daily Intake (ADI) or determined on the basis of other criteria, to be safe by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Additionally, the substance must have an International Numbering System (INS) designation by Codex (Section 1.1 of the Preamble to the GSFA).

this substance is for its use as a filtering aid and processing aids are not included in the GSFA. New Zealand also requested the inclusion of carbon dioxide (INS 290) in food category 14.2.3 (Grape wines) for use in accordance with good manufacturing practices (GMP). However, this provision is already included in the GSFA at Step 7.[8]

5. In their submitted comments to CL 2012/5-FA, Part B, Point 10, CCC requested that a provision for saccharins (INS 954(i) – (iv)) in food category 14.1.3.4 (Concentrates for vegetable nectar) at 80 mg/kg be included in the GSFA. However, this provision is already included in the GSFA at Step 6.[9] Therefore, the proposed provision has not been included in Appendix 1 but CCC's comment is included in Appendix 3.

6. In their comments to the GSFA eWG, OIV also requested the inclusion of calcium tartrate in food category 14.2.3 (Grape wines) in accordance with good manufacturing practices (GMP). As noted above (para. 4), calcium tartrate does not meet the criteria for inclusion in the GSFA as it has not been assigned a full ADI by JECFA. Therefore, the proposed provision has not been included in Appendix 2.

7. In their comments to the GSFA eWG, ICGMA recommended the inclusion of sodium potassium hexametaphosphate (INS 452(vi)) and tartaric acid esters of mono- and di-glycerides of fatty acids (INS 472d) in food category 10.2.1 (Liquid egg products) for use as thickeners in accordance with GMP. These substances have not been assigned a full ADI by JECFA, and therefore, do not meet the criteria for inclusion in the GSFA. Therefore, these proposed provisions have not been included in Appendix 2.

[8] Note 60 ("If used as a carbonating agent, the CO_2 in the finished wine shall not exceed 39.2 mg/kg.") is associated with the GSFA provision for Carbon dioxide in food category 14.2.3.

[9] Note 127 ("As served to the consumer.") and Note 161 ("Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.") are associated with the GSFA provision for Saccharins in food category 14.1.3.4.

APPENDIX 1: SUMMARY OF COMMENTS SUBMITTED IN RESPONSE TO CL 2012/5-FA, PART B, POINT 10

8. In the following tables, revisions to existing provisions in the GSFA are noted as follows: deletions are denoted by ~~strikethrough~~ font, and additions or changes are noted in **bold** font. A completely new provision to be included in the GSFA has the "Step" column blank.

Ascorbyl Esters (INS 304, 305)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
13.2	Complementary foods for infants and young children	~~100~~ **200**	Notes 10, 15 & **ZZ**	Adopted 2010	**Brazil:** INS 304 only for conformity with CODEX STAN 74-1981. Increases adopted ML of 200 mg/kg.

Note 10: As ascorbyl stearate.
Note 15: Fat or oil basis.
Note ZZ: INS 304 (ascorbyl palmitate only).

Aspartame (INS 951)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
6.8.1	Soy-based beverages	1500			**CCC:** Adds sweetness to improve flavour.

Aspartame-Acesulfame Salt (INS 962)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
01.3.2	Beverage whiteners	~~4540~~ **2000**	Note 113	3	CCC, ISA
01.4.4	Cream analogues	~~1550~~ **1000**	Note 119	3	CCC, ISA
01.5.2	Milk and cream powder analogues	~~3100~~ **1000**	~~Note 119~~ **Note 113**	3	CCC, ISA
01.6.5	Cheese analogues	~~790~~ **350**	Note 113	3	CCC
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	~~1550~~ **1000**	Note 119	3	CCC., ISA
03.0	Edible ices, including sherbet and sorbet	~~1550~~ **1000**	~~Notes 113 & 161~~ **Note 119**	3	CCC, ISA
04.1.2.1	Frozen fruit	~~1130~~ **500**	Note 113	3	CCC, ISA
04.1.2.2	Dried fruit	~~1130~~ **500**	Note 113	3	CCC, ISA
04.1.2.3	Fruit in vinegar, oil or brine	~~450~~ **200**	Notes 113 ~~& 144~~	3	CCC
04.1.2.6	Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5	~~2270~~ **1000**	~~Notes 113 & 138~~ **Note 119**	3	CCC, ISA
04.1.2.7	Candied fruit	~~1130~~ **500**	Note 113	3	CCC, ISA
04.1.2.10	Fermented fruit products	~~790~~ **350**	Note 113	3	CCC, ISA
04.1.2.11	Fruit fillings for pastries	~~790~~ **350**	Note 113	3	CCC, ISA
04.1.2.12	Cooked fruit	~~1130~~ **500**	Note 113	3	CCC, ISA
04.2.2.4	Canned or bottled (pasteurized) or retort pouch vegetables (including	~~790~~ **350**	Note 113	3	CCC

Aspartame-Acesulfame Salt (INS 962)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
	mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds				
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)	~~4660~~ **1000**	Note 119	3	CCC
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	~~2270~~ **1000**	Note 113	3	CCC
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	350	Notes **97 &** 113		CCC **ISA:** Add Note 97
05.1.2	Cocoa mixes (syrups)	~~1130~~ **350**	Notes **97** & 113	3	CCC **Costa Rica, ICGMA, ISA:** Add Note 97
05.1.3	Cocoa-based spreads, including fillings	~~4540~~ **1000**	Notes 113 ~~& 145~~	3	Costa Rica, CCC, ICGMA, ISA
05.1.4	Cocoa and chocolate products	~~2270~~ **500**	Notes 113 ~~& 145~~	3	Costa Rica, CCC, ICGMA, ISA
05.2.1	Hard candy	500	Notes 113 **& 156**		Costa Rica, ICGMA, ISA **CCC:** Add Note 156
05.2.2	Soft candy	1000	Note 113		Costa Rica, CCC, ICGMA, ISA
05.2.3	Nougats and marzipans	1000	Note 113		Costa Rica, CCC, ICGMA, ISA
05.3	Chewing gum	~~4540~~ **5000**	Notes ~~68 &~~ 113	3	Costa Rica, CCC, ICGA, ICGMA, ISA
05.4	Decorations (e.g., for fine bakery wares), toppings (nonfruit) and sweet sauces	~~1130~~ **500**	Note 113	3	Costa Rica, CCC, ICGMA, ISA
06.3	Breakfast cereals, including rolled oats	~~1550~~ **1000**	Notes 119 ~~& 145~~	3	CCC, ISA
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	~~790~~ **350**	Notes 113 ~~& 145~~	3	CCC, ISA
07.1	Bread and ordinary bakery wares	~~2270~~ **1000**	Note 113	3	CCC, ISA
10.4	Egg-based desserts (e.g. custard)	~~790~~ **350**	Notes 113 ~~& 145~~	3	CCC, ISA
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1000	Notes 113 & 159		ISA
12.2.2	Seasonings and condiments	~~3100~~ **2000**	~~Note 113~~ **Note 119**	3	CCC
12.4	Mustards	~~540~~ **350**	Note 119	3	CCC
12.5	Soups and broths	~~250~~ **110**	Notes 113 ~~& 138~~	3	CCC
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.4 and 05.1.3	~~1550~~ **350**	~~Notes 113 & 145~~ **Note 119**	3	CCC
14.1.3.2	Vegetable Nectar	350	Note 113		ISA
14.1.3.4	Concentrates for vegetable nectar	~~3100~~ **350**	Notes 113 **& 127**	3	ISA
14.1.4	Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks	~~930~~ **600**	Notes 119 ~~& 145~~	3	CCC, ISA

Aspartame-Acesulfame Salt (INS 962)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	~~1360~~ **600**	~~Note 113~~ **Notes 119 & 160**	3	CCC **ISA:** Add Note 160
15.0	Ready-to-eat savouries	~~770~~ **500**	Notes 119 ~~& 144~~	3	CCC

Note 68: For use in products with no added sugar only.
Note 97: In the finished product/final cocoa and chocolate product.
Note 113: Use level reported as acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68.)
Note 119: Use level reported as aspartame equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.64). Combined use of aspartame-acesulfame salt with individual aspartame or acesulfame potassium should not exceed the individual maximum levels for aspartame or acesulfame potassium (the reported maximum level can be converted to acesulfame potassium equivalents by multiplying by 0.68).
Note 127: As served to the consumer.
Note 138: For use in energy reduced products only.
Note 144: For use in sweet and sour products only.
Note 145: Products are energy-reduced or with no added sugar.
Note 156: For use in microsweets and breath freshening mints at 1500 mg/kg.
Note 159: For use in pancake syrup and maple syrup only.
Note 160: For use in ready-to-drink products and pre-mixes for ready-to-drink products only.
Note 161: Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.

Brown HT (INS 155)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
08.4	Edible casings (e.g., sausage casings)	5000			**EU:** To deliver effective amount of colour. Used only in casings for particular sausages. The GSFA currently contains a provision in food category 08.0 (Meat and meat products, including poultry and game) at 500 mg/kg, with Note 16 ("For use in glaze, coatings or decorations for fruit, vegetables, meat or fish.") at Step 7.

Calcium Hydroxide (INS 526)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
~~02.2.1~~	~~Butter~~	~~GMP~~		Adopted 2008	**EU:** Revoke. No technological justification for use of acidity regulators in butter.

Carmines (INS 120)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
08.4	Edible casings (e.g., sausage casings)	~~500~~ **10000**	Note 16	Adopted 2005	**EU:** Increase ML. To deliver effective amount of colour. Used only in casings for particular sausages.

Note 16: For use in glaze, coatings or decorations for fruit, vegetables, meat or fish.

Carotenoids (INS 160a(i), 160a(iii), 160e, 160f)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
08.4	Edible casings (e.g., sausage casings)	~~100~~ **10000**		Adopted 2011	**EU:** Increase ML. To deliver effective amount of colour. Used only in casings for particular sausages.

Curcumin (INS 100(i))					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
08.4	Edible casings (e.g., sausage casings)	~~500~~ **2000**	Note 16	**7**	**EU:** To deliver effective amount of colour. Used only in casings for particular sausages.

Note 16: For use in glaze, coatings or decorations for fruit, vegetables, meat or fish.

Iron Oxides (INS 172(i), (ii), (iii))					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
08.4	Edible casings (e.g., sausage casings)	~~1000~~ **5000**	Note 72	Adopted 2005	**EU:** Increase ML. To deliver effective amount of colour. Used only in casings for particular sausages.

Note 72: Ready-to-eat basis.

Lauric Arginate Ethyl Ester (INS 243)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
08.2.1	Non-heat treated processed meat, poultry, and game products in whole pieces or cuts	200			**USA:** Inhibits growth of microoganisms in processed meat and poultry products.
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	200			**USA:** Inhibits growth of microoganisms in processed meat and poultry products.
08.2.3	Frozen processed meat, poultry, and game products in whole pieces or cuts	200	~~Note 3~~	3	**USA:** Inhibits growth of microoganisms in processed meat and poultry products.
08.3.1	Non-heat treated processed comminuted meat, poultry, and game products	200			**USA:** Inhibits growth of microoganisms in processed meat and poultry products.
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	200			**USA:** Inhibits growth of microoganisms in processed meat and poultry products.
08.3.3	Frozen processed comminuted meat, poultry, and game products	200	~~Note 3~~	3	**USA:** Inhibits growth of microoganisms in processed meat and poultry products.

Note 3: Surface treatment.

Neotame (INS 961)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
14.1.3.1	Fruit nectars	65			**CCC:** Improves taste without adding calories. **ISA:** Products are typically heat-treated, and neotame has greater thermal stability, so that less sweetener is added later in the process.
14.1.3.3	Concentrates for fruit nectars	65			**CCC:** Improves taste without adding calories. **ISA:** Products are typically heat-treated, and neotame has greaterr thermal stability, so that less sweetener is addeded later in the process.

Sodium Carbonate (INS 500(i))					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
02.2.1	Butter	GMP	**Note CC**	Adopted 2008	**EU:** No technological justification for use of acidity regulators in butter. Sodium carbonates may be used to stabilize pH of specific products (e.g., soured cream butter).

Note CC: Use as a pH stabilizer in soured cream butter only.

Sodium Hydrogen Carbonate (INS 500(ii))					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
02.2.1	Butter	GMP	**Note CC**	Adopted 2008	**EU:** No technological justification for use of acidity regulators in butter. Sodium carbonates may be used to stabilize pH of specific products (e.g., soured cream butter).

Note CC: Use as a pH stabilizer in soured cream butter only.

Sodium Hydroxide (INS 524)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
~~02.2.1~~	~~Butter~~	~~GMP~~		Adopted 2008	**EU:** Revoke. No technological justification for use of acidity regulators in butter.

Sorbates (INS 200, 201, 202, 203)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
08.4	Edible casings (e.g., sausage casings)	~~200~~ **10000**	Notes 42 & ~~222~~ **222REV**	7	**EU:** Increase ML. Potassium sorbate (INS 202) only is used to prevent mold growth on the casing; no function in the final sausage.

Note 42: As sorbic acid
Note 222: For use in collagen-based casings with a water activity greater than 0.6 only.
Note 222REV: INS 202 (Potassium sorbate) only for use in collagen-based casings with a water activity greater than 0.6 only.

Sucralose (Trichlorogalactosucrose) (INS 955)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
01.5.2	Milk and cream powder analogues	~~400~~ **580**		3	**CCC:** 580 mg/kg. Sweetens without added carbohydrates and calories. Added carbohydrates may result in browning reactions that impair the appearance of the product. Intense sweeteners may be used in this food category. ML based on Japanese standard. **ISA:** 400 mg/kg. Sweetens without added carbohydrates and calories. Added carbohydrates may result in browning reactions that impair the appearance of the product. Intense sweeteners may be used in this food category.

Tartrazine (INS 102)					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
08.4	Edible casings (e.g., sausage casings)	300			**EU:** To deliver effective amount of colour. Used only in casings for particular sausages. The GSFA currently contains a provision in food category 08.0 (Meat and meat products, including poultry and game) at 500 mg/kg, with Note 4 (“For decoration, stamping, marking or branding the product.”) and Note 16 (“For use in glaze, coatings or decorations for fruit, vegetables, meat or fish.”) at Step 7.

APPENDIX 2: SUMMARY OF COMMENTS AND RECOMMENDATIONS TO THE ELCTRONIC WORKING GROUP OF THE GSFA – NEW PROPOSALS FOR TABLE 3 ADDITIVES WITH THE FUNCTION "ACIDITY REGULATOR" OR "EMUSIFIER, STABILIZER, THICKENER"

Acetic and fatty acid esters of glycerol (INS 472a)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
06.4.1	Fresh pastas and noodles and like products	GMP		**EFEMA, IFAC:** as thickener

Acetylated distarch adipate (INS 1422)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
06.4.1	Fresh pastas and noodles and like products	GMP		**ICGMA:** For use as thickener
06.4.2	Dried pastas and noodles and like products	GMP		**ICGMA:** For use as thickener

Acetylated distarch phosphate (INS 1414)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
06.4.1	Fresh pastas and noodles and like products	GMP		**ICGMA:** For use as thickener
06.4.2	Dried pastas and noodles and like products	GMP		**ICGMA:** For use as thickener

Aluminium sulfate (INS 520)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
10.2.1	Liquid egg products	100	6	**ICGMA:** as EMULSIFIER - Protein Coagulation Suppressant (Crystallization inhibitor.) The aluminum binds with egg proteins to help maintain protein solubility during the pasteurization/heating process.
10.2.2	Frozen egg products	100	6	

Note 6: As aluminium

Ammonium hydroxide (INS 527)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
04.1.1.2	Surface treated fresh fish	GMP		**Brazil:** Brazil agrees that the use of acidity regulators in this FC is generally not justified. However, INS 527 ammonium hydroxyde is necessary for the surface treatment of fresh fruits. The use is concomitant with glazing agents, especially waxes, which there are several authorized for this subcategory. The technological function "carrier" could be added to INS 527. Brazil will make the proposal for addition of the function "carrier" to INS 527 within the INS eWG, and would like to propose its provision for food category 04.1.1.2 at the maximum use level of GMP.

Calcium sulfate (INS 516)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
10.2.1	Liquid egg products	GMP		**ICGMA:** as thickener

Carrageenan (INS 407)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
01.2.1.2	Fermented milks (plain), heat-treated after fermentation	GMP		**Marinalg:** for consistency with Codex Standard 243-2003

Citric and fatty acid esters of glycerol (INS 472c)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
06.4.1	Fresh pastas and noodles and like products	GMP		**EFEMA, IFAC:** as thickener

Dextrins, roasted starch (INS 1400)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
06.4.2	Dried pastas and noodles and like products	GMP		**ICGMA:** For use as thickener
10.2.1	Liquid egg products	GMP		**ICGMA:** For use as thickener
10.2.2	Frozen egg products	GMP		**ICGMA:** For use as thickener

Distarch phosphate (INS 1412)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
08.1	Fresh meat, poultry, and game	GMP		**ICGMA:** modified food starches are used as thickeners with fresh meats to manage texture (thickener), in injected and tumbled poultry, and in sausage-type products.

Hydroxypropyl distarch phosphate (INS 1442)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
08.1	Fresh meat, poultry, and game	GMP		**ICGMA:** modified food starches are used as thickeners with fresh meats to manage texture (thickener), in injected and tumbled poultry, and in sausage-type products.

Lactic and fatty acid esters of glycerol (INS 472b)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
06.4.1	Fresh pastas and noodles and like products	GMP		**EFEMA, IFAC:** as thickener

Lecithin (INS 322(i))					
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Step**	**Comment Summary**
01.8.2	Dried whey and whey products, excluding whey cheese	30000			**IFAC:** Lecithin is currently widely used on whey protein concentrate and whey protein isolate for instantizing at a rate of 0.3-2.0%. The instantizing function of lecithin is required in this application to disperse the dried whey and to provide stabilizing and thickening properties.

Mono- and di-glycerides of fatty acids (INS 471)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
01.2.1.2	Fermented milks (plain), heat-treated after fermentation	GMP		**EFEMA:** For alignment with EU legislation and Codex Standard 243-2003. Emulsifiers are advantageous in fermented dairy products for stabilization of the protein prior to heat treatment and optimization of viscosity, preventing physical spoilage during transport and storage, all while improving mouthfeel, cooking and baking stability."
10.2.1	Liquid egg products	GMP		**ICGMA:** As thickener

Monostarch phosphate (INS 1410)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
08.1	Fresh meat, poultry, and game	GMP		**ICGMA:** modified food starches are used as thickeners with fresh meats to manage texture (thickener), in injected and tumbled poultry, and in sausage-type products.

Pectins (INS 440)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
01.2	Fermented and renneted milk products (plain), excluding food category 01.1.2 (dairy-based drinks)	GMP		**IFAC:** pectins are approved at GMP in all sub-categories.
14.1.2	Fruit and vegetable juices	3000		**Costa Rica, ICGMA:** used to thicken and adjust mouth feel and to stabilize
14.1.3	Fruit and vegetable nectars	3000		**Costa Rica, ICGMA:** used to thicken and adjust mouth feel and to stabilize

Phosphated distarch phosphate (INS 1413)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
08.1	Fresh meat, poultry, and game	GMP		**ICGMA:** modified food starches are used as thickeners with fresh meats to manage texture (thickener), in injected and tumbled poultry, and in sausage-type products.

Sodium carboxymethyl cellulose (Cellulose gum) (INS 466)				
Food Category No.	**Food or Food Category**	**Max Level**	**Notes**	**Comment Summary**
14.2.3	Grape wines	100 mg/l		**OIV:** for use in white and sparkling wines in order to contribute to tartaric stabilization

Starches, enzyme treated (INS 1405)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
08.1	Fresh meat, poultry, and game	GMP		**ICGMA:** modified food starches are used as thickeners with fresh meats to manage texture (thickener), in injected and tumbled poultry, and in sausage-type products.

Starch acetate (INS 1420)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
06.4.1	Fresh pastas and noodles and like products	GMP		**ICGMA:** For use as thickener
06.4.2	Dried pastas and noodles and like products	GMP		**ICGMA:** For use as thickener
08.1	Fresh meat, poultry, and game	GMP		**ICGMA:** modified food starches are used as thickeners with fresh meats to manage texture (thickener), in injected and tumbled poultry, and in sausage-type products.

Starch sodium octenyl succinate (INS 1450)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
10.2.1	Liquid egg products	GMP		**ICGMA:** as thickener
10.2.2	Frozen egg products	GMP		**ICGMA:** as thickener
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	GMP		**ICGMA:** As thickener

Tartrates (INS 334, 335(i), 335(ii), 336(i), 336(ii), 337)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
14.2.3	Grape wines	4000		**OIV:** The OIV has admitted the addition of L(+) tartaric acid (INS No334) in wines in order to increase the titration acidity and the actual acidity (decreasing pH) by adding organic acids, also to contribute to the reduction of excessive levels of calcium. Therefore the OIV recommends the addition of L(+) tartaric acid in the list of Acidity regulators for the Food Category 14.2.3 Grape wines.

Tartrates (INS 334, 335(i), 335(ii), 336(i), 336(ii), 337)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
				For de-acidification, the OIV has admitted the addition, in wines, of neutral potassium tartrate, potassium hydrogen carbonate or calcium carbonate containing possibly small quantities of the calcium double salt of L(+) tartaric and L(-)malic acids for decreasing the acidity and the actual acidity (increase of the pH). Therefore the OIV recommends the addition of Potassium L(+) Tartrate (INS No 336ii) in the list of Acidity regulators for the Food Category 14.2.3 Grape wines.

Xanthan gum (INS 415)				
Food Category No.	**Food or Food Category**	**Max Level (mg/kg)**	**Notes**	**Comment Summary**
14.1.2	Fruit and vegetable juices	3000		**Costa Rica, ICGMA:** used to thicken and adjust mouth feel and to stabilize
14.1.3	Fruit and vegetable nectars	3000		**Costa Rica, ICGMA:** used to thicken and adjust mouth feel and to stabilize

APPENDIX 3 – FULL TECHNOLOGICAL JUSTIFICATION PROVIDED IN SUPPORT OF COMMENTS IN RESPONSE TO CL 2012/5-FA, PART B, POINT 10

Brazil

Brazil requests the inclusion of the following provision at step 3 in the GSFA, regarding INS 304 ascorbyl palmitate:

Food Cat No.	Food Category	Max Level	Step	Brazil
13.2	Complementary foods for infants and young children	200 mg/kg	3 Note 10 & 15	Brazil suggests increasing the adopted ML of 100 mg/kg, to 200 mg/kg, only for INS 304, for consistency with CODEX STAN 074/1981, which allows only INS 304.

Costa Rica

First Comment:

Costa Rica does not have new proposals in response to the request in this section.

Second Comment:

Costa Rica appreciates the opportunity to provide comments on proposals for new food additive provisions and/or revision of food additive provisions in the GSFA, on which the following is provided:

Aspartame-Acesulfame Salt (INS 962)

The combination of aspartame and acesulfame in a single salt provides a unique synergistic effect that results in a longer-lasting sweetness intensity in the product. In addition, it is more stable to degradation under storage conditions, compared to other sweeteners.

It is completely safe and complies with the requirements of Good Manufacturing Practices. It is very soluble, and slightly hygroscopic, which enables it to be a very stable sweetener in low-moisture foods, such as confectionary product; for example, it allows chewing gum to maintain its characteristic taste.

The following new provisions are requested for inclusión at Step 3 of the procedure:

05.1.2 Cocoa mixes (syrups):	350 mg/kg (Note 97*, Note 113**)
05.1.3 Cocoa-based spreads, including fillings:	1,000 mg/kg (Note 113)
05.1.4 Cocoa and chocolate products:	500 mg/kg (Note 113)
05.2.1 Hard Candy	500 (Note 113)
05.2.2 Soft Candy	1,000 (Note 113)
05.2.3 Nougats and marzipans	1,000 (Note 113)
05.3 Chewing gum	5,000 mg/kg (Note 113)
05.4 Decorations (e.g., for fine bakery wares), toppings (nonfruit) and sweet sauces	500 mg/kg (Note 113)

* **Note 97**: In the finished product/final cocoa and chocolate product.
** **Note 113**: Use level reported as acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68.)

European Union

The European Union would like to submit the following proposals:

Category 02.2.1 (butter):

(1) The EU proposes the removal of the following acidity regulators:

- Sodium hydroxide 524
- Calcium hydroxide 526

Reasoning: No satisfactory technical justification has been provided for the addition of acidity regulators to butter. In the absence of any supporting justification, we propose that these additives should be removed from this category.

(2) The EU proposes to restrict the use of the following acidity regulators:

- Sodium carbonate 500 (i)
- Sodium hydrogen carbonate 500 (ii)

Reasoning: No satisfactory technical justification has been provided for the addition of acidity regulators to butter. The EU takes note that sodium carbonates might be used to stabilise pH of certain very specific products – i.e. soured cream butter. Therefore, the EU proposes that the use of sodium carbonates is restricted by a footnote to soured cream butter only.

In Category 08.4 (edible casings) the following additional colours are requested:

100	Curcumin	2000 mg/kg
102	Tartrazine	300 mg/kg
155	Brown HT	5000 mg/kg

In category 08.4 (edible casings), increased levels of the following permitted colours are requested:

172	Iron oxides	5000 mg/kg
120	Carmines	10000 mg/kg
160a(i),a(iii),e	CAROTENOIDs*	10000 mg/kg

* The EU notes that the group "Carotenoids" includes INS 160f Carotenoic acid, ethyl ester, beta-apo-8'-. According to the EU's knowledge this food additive is not used anymore. If this is confirmed by other Codex members, the group Carotenoids shall be revised to exclude INS 160f. Then INS 160f could be excluded also from the Re-evaluation of Food Additives by the Joint (FAO/WHO) Expert Committee on Food Additives.

Technical justification

As collagen casings are extremely thin and translucent, the colour addition levels in the casing need to be high on a concentration basis to deliver an effective level of colour.

Though casings contribute less than 1% (typically 0.5%) by weight they do represent the most of the visible aspect of a sausage. The current permitted levels provided in the GSFA, particularly the natural colours, are insufficient to provide any realistic colour impact in the final product. Colours are only added to some casings as needed by the particular sausage application.

In category 08.4 (edible casings) the following preservative is requested for collagen-based casings with water activity greater than 0,6 only.

202	Potassium sorbate	10000 mg/kg

Technical justification

Potassium sorbate (INS 202) is used to prevent mould growth on casings during ambient storage. The potassium sorbate has no function in the final sausage as a whole but on the surface only. Industry test data demonstrate that a level of 10,000 mg/kg is needed to guarantee mould inhibition

New Zealand

Grape Wine Cat 14.2.3

INS	Additive name	Level	Function	Technological justification	Usage	JECFA
354	Calcium tartrate	GMP	Acidity Regulator / stabiliser	Calcium tartrate seeding is used for tartrate stabilisation and deacidification. A 60/40 blend of calcium carbonate and tartaric acid is used. Mixed and washed three times to remove impurities. It is added to clear racked wine at a rate of 16 grams/gallon. This will render wine tartrate stable within 24-48 hours without chilling, reducing tartrate by 65-70%. On average, this will reduce total acidity by 0.1 % and will not result in calcium tartrate instability		Evaluated in 1983, no ADI allocated. Meeting: 27 Report: TRS 696-JECFA 27/28 Tox Monograph: NOT PREPARED Specification: NOT PREPARED
290	Carbon dioxide	GMP	Carbonating Agent	Carbon dioxide is a gas produced during alcoholic and malolactic fermentation of grape juice and wine. It is a cost effective preservative as well as processing aid to prevent oxidation of wine by itself or in combination with nitrogen. It is also added to some wines to make carbonated wine.	Approved in all major producers, including , US, Europe, Australia and New Zealand for use in wine.	**Evaluation year**: **1985** ADI: NOT SPECIFIED Meeting: 49 Specs Code: R (1997) Report: TRS 733-JECFA 29/39 Tox Monograph: NOT PREPARED Specification: COMPENDIUM ADDENDUM 5/FNP 52 Add.5/25 (1997); FAO JECFA Monographs 1 vol.1/301

INS	Additive name	Level	Function	Technological justification	Usage	JECFA
						Previous Years: 1989, FNP 34-JECFA 29/43; COMPENDIUM/369. R,T 1983, FNP 28-JECFA 27/19. R,T 1979, TRS 648-JECFA 23/19, NOT PREPARED, NOT PREPARED. ADI NOT SPECIFIED. NS. O (CARBON DIOXIDE, LIQUID) 1976, FNS 1/TRS 599-JECFA 20/12, FAS 11/FNS 1B-JECFA 20/16. N,T (EXCEPT
353	Metatartaric acid	GMP	Prevents Potassium bitartrate precipitation	The presence of potassium bitartrate crystals in wine is not a safety or wine tasting issue but rather one of aesthetics. There are two current stabilisation treatments used to prevent their formation in wine bottles. The first is called cold stabilisation and it involves keeping wine at very low temperature for a long period of time to promote early crystallisation of the tartrate (which is removed by filtration before bottling). The second method involves the use of metatartaric acid which is an approved food additive for this purpose. the use of mannoproteins extracted from yeast cell walls as a food additive for wine to inhibit potassium bitartrate crystallisation which commonly occurs in wine bottles is an alternative treatment to the usual time-consuming and expensive wine-making practices currently undertaken to stabilise wine.	Metatartaric acid No JECFA ADI Do not include	GMP
181	Tannins	GMP	Mouth feel ; stabiliser	Tannins are naturally occuring in wine. Tannins are added for the following purposes and problem corrections: - Redox buffer - Raisined fruit - Sun-damaged fruit - Unripe grape tannins - Structural/textural, mouthfeel modification - Increased substrate for microoxidation - Limit the activity of laccase - Help to precipitate proteins - Help to modify aromas, including vegetative aromas - Help increase aging potential - Possibly to help stabilize red wine color Of the above listed purposes for tannin addition, the most common, perhaps, is for mouthfeel modification.	Approved in all major producers, including , US, Europe, Australia and New Zealand for use in wine. The JECFA Monographs deal only with hydrolysable gallotannins, a small class of what might be labelled as tannin; or used traditionally by the wine industry as tannin. The Organisation Internationale de la Vigne et du Vin (OIV) International Oenological Codex (Edition 2006) specified that tannins must be derived from nutgalls, wood rich in tannin, or grape seeds. In addition, it states that the addition of these tannins must not change the olfactory properties or colour of the wine. Under these specifications, grape	**Evaluation year**: **1989** ADI: NOT SPECIFIED Comments: For use as a filtering aid where the application of good manufacturing practice ensures that it is removed from food after use Meeting: 35 Specs Code: R (1992) Report: TRS 789-JECFA 35/27 Tox Monograph: FAS 70.39/NMRS 48A-JECFA 14/82 (1970) Specification: COMPENDIUM ADDENDUM 12/FNP 52 Add. 12/68 (METALS LIMITS) (2004). R; FAO JECFA Monographs 1 vol.3/481 Previous Years: 1992, COMPENDIUM ADDENDUM 1/FNP 52 Add.1/117. R 1989, FNP 49-JECFA 35/70; COMPENDIUM/1471. R,T 1987, TRS 759-JECFA 31/32, FNP 38-JECFA 31/250, FAS 70.39/NMRS 48A-JECFA

INS	Additive name	Level	Function	Technological justification	Usage	JECFA
					skin derived tannins must be added as grape skin extract rather than tannin and that tannins derived from roots, shoots, leaves and fruits would not be permitted (ie sumac, valorea, tara, teri, myrobalan, gambir and many others such as cocoa, pomegranate, tea and persimmon).	14/82 (1970). ADI NOT SPECIFIED (TEMPORARY; FOR USE AS A PROCESSING AID). NS/TE. R,T
	Yeast mannoproteins	400 mg/kg	Reduce wine astringency and increase wine smoothness and body	Stabiliser Yeast mannoproteins are added to wine as a food additive to inhibit the formation of potassium bitartrate crystals which are commonly formed in bottled wine. The presence of potassium bitartrate crystals in wine is not a safety or wine tasting issue but rather one of aesthetics. There are two other stabilisation treatments used to prevent their formation in wine bottles. The first is called cold stabilisation and it involves keeping wine at very low temperature for a long period of time to promote early crystallisation of the tartrate (which is removed by filtration before bottling). The second method involves the use of metatartaric acid which is an approved food additive for this purpose Yeast mannoproteins inhibit tartrate crystallisation in the wine bottle. Wine is treated with yeast mannoproteins in the range of 100-300 mg/l (the maximum proposed treatment level being 300 mg/l)	Oeno 26/2004 Yeast mannoproteins are approved for use to stabilise wine in a number of countries (in the European Union and Argentina) and by the international organisation, the International Organisation of Vine and Wine (OIV, Office International de la Vigne et du Vin). The Agreement between Australia and the European Community on Trade in Wine, and Protocol (1994) allows the use of preparations of yeast cell wall (up to a level of 400 mg/l) for Australian and European produced wine.	Mannoproteins are extracted from purified yeast (*Saccharomyces cerevisiae*) cell walls, via enzymatic extraction using β-glucanase. The mannoprotein preparation of this Application has an apparent molecular weight of around 40 kDa.The mannoprotein preparation is produced by the β-glucanase enzymatic extraction of *Saccharomyces cerevisiae* yeast cell walls. The β-glucanase enzyme preparation is approved for use as a food processing aid in Australia, being listed in the Table to clause 17 of Standard 1.3.3 – Processing Aids of the Code. The enzyme hydrolyses the yeast cell wall which then allows the mannoproteins to be solubilised. Subsequently the enzyme digestion is ultrafiltered to remove insoluble cell wall material and the mannoprotein preparation concentrated.

United States of America

The United States appreciates this opportunity, and provides proposals for the inclusion of new uses for lauric arginate ethyl ester (LAEE, INS 243) as proposed draft provisions in the GSFA for consideration at the forthcoming 45th Session of the Codex Committee on Food Additives (CCFA). This proposal is submitted according to the *Procedure for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives* in the Procedure Manual, and the following information is being provided in accordance with these requirements.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated LAEE at its 69th Meeting (2008), and established an acceptable daily intake (ADI) of 0-4 mg/kg bw. Specifications for LAEE were prepared at the 71st JECFA (2009) and published in FAO JECFA Monographs 7 (2009). The International Numbering System (INS; CAC/GL 36-1989) associates the technological purpose of "preservative" and INS No. 243 with LAEE.

The following new uses of LAEE as a preservative are requested for inclusion as proposed draft provisions in Tables 1 and 2 of the GSFA:

Food Cat. No.	Food Category	Maximum Level
08.2.1	Non-heat treated processed meat, poultry, and game products in whole pieces or cuts	200 mg/kg
08.2.2	Heat-treated processed meat, poultry, and game products in whole pieces or cuts	200 mg/kg
08.2.3	Frozen processed meat, poultry, and game products in whole pieces or cuts	200 mg/kg
08.3.1	Non-heat treated processed comminuted meat, poultry, and game products	200 mg/kg
08.3.2	Heat-treated processed comminuted meat, poultry, and game products	200 mg/kg

08.3.3	Frozen processed comminuted meat, poultry, and game products	200 mg/kg

LAEE, a cationic surfactant, has a wide spectrum of activity against Gram positive and Gram negative bacteria, and against yeasts and molds. LAEE inhibits the growth of microorganisms (e.g. *Listeria*) in processed meat and poultry products. Information supporting the efficacy of LAEE is presented in the attachment. Detailed study results can be provided if needed.

The use of LAEE as a preservative in processed meat and poultry products is technological justified according to Section 3.2(c) of the Preamble to the GSFA, "to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer."

The use of this additive meets the general principles for food additive safety in Section 3.1 of the Preamble to the GSFA. The additive has been evaluated by JECFA, the ADI is taken into account, and the quantity of the additive used in the food is at the appropriate level to achieve the intended technical effect.

The consumer would not be deceived by the use of LAEE in the proposed products. The name of the additive would be included in the list of ingredients on the food label. Further, consumers are familiar with the use of preservatives in foods to maintain their quality and stability.

Calorie Control Council

Further to the above requests for the Aspartame-Acesulfame salt, the CCC requests the inclusion of the following new provisions at Step 3 in the GSFA for INS 962 Aspartame-Acesulfame salt. The CCC urges the CCFA to adopt the use of the aspartame-acesulfame salt in food categories 05.2.1, 05.2.2, and 05.2.3 as products in these categories containing the aspartame-acesulfame salt are currently being used internationally.

Food Cat No.	Food Category	Max Level	Step	Comments
05.2.1	Hard candy, including microsweets	500 mg/kg Note 156	3	The aspartame-acesulfame salt may be used to sweeten hard candy without adding calories. The amount requested is needed to achieve the appropriate technical effect. The CCFA has agreed that intense sweeteners may be used in this food category and has already adopted provisions for both aspartame and acesulfame K individually in this food category.
05.2.2	Soft candy	1000 mg/kg	3	The aspartame-acesulfame salt may be used to sweeten soft candy without adding calories. The amount requested is needed to achieve the appropriate technical effect. The CCFA has agreed that intense sweeteners may be used in this food category and has already adopted provisions for both aspartame and acesulfame K individually in this food category.
05.2.3	Nougats and marzipans	1000 mg/kg	3	The aspartame-acesulfame salt may be used to sweeten nougats and marzipans without adding calories. The amount requested is needed to achieve the appropriate technical effect. The CCFA has agreed that intense sweeteners may be used in this food category and has already adopted provisions for both aspartame and acesulfame K individually in this food category.

Note 156: For use in microsweets and breath freshening mints at 2500 mg/kg.

The CCC also requests that the CCFA adopt additional provisions for the aspartame-acesulfame salt for which provisions for aspartame and acesulfame K have been adopted. The table below provides these provisions and the amounts adopted for aspartame and acesulfame K as well as amounts requested for the aspartame-acesulfame salt with the appropriate footnote. The CCC urges the CCFA to adopt the use of the aspartame-acesulfame salt in these food categories, especially food category 05.3 Chewing Gum as products in this category containing the aspartame-acesulfame salt are currently available internationally.

ASPARTAME-ACESULFAME SALT				
Food Category No.	**Food Category**	**Aspartame mg/kg**	**Acesulfame K mg/kg**	**Aspartame-Acesulfame Salt mg/kg**
01.3.2	Beverage whiteners	6000	2000	2000 Note 113
01.4.4	Cream analogues	1000	1000	1000 Note 119
01.5.2	Milk and cream powder analogues	2000	1000	1000 Note 113
01.6.5	Cheese analogues	1000	350	350 Note 113
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	1000	1000	1000 Note 119

ASPARTAME-ACESULFAME SALT				
Food Category No.	**Food Category**	**Aspartame mg/kg**	**Acesulfame K mg/kg**	**Aspartame-Acesulfame Salt mg/kg**
03.0	Edible ices, including sherbet and sorbet	1000	800	1000 Note 119
04.1.2.1	Frozen fruit	2000	500	500 Note 113
04.1.2.2	Dried fruit	2000	500	500 Note 113
04.1.2.3	Fruit in vinegar, oil or brine	300	200	200 Note 113
04.1.2.6	Fruit-based spreads (e.g. chutney) excluding products of food category 04.1.2.5	1000	1000	1000 Note 119
04.1.2.7	Candied fruit	2000	500	500 Note 113
04.1.2.10	Fermented fruit products	1000	350	350 Note 113
04.1.2.11	Fruit fillings for pastries	1000	350	350 Note 113
04.1.2.12	Cooked fruit	1000	500	500 Note 113
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	1000	350	350 Note 113
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)	1000	1000	1000 Note 119
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 06.8l6, 06.8.7, 12.9.1, 12.9.2.1 and 12.9.2.3	2500	1000	1000 Note 113
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	3000	350	350 Note 113
05.1.2	Cocoa mixes (syrups)	1000	350	350 Note 113
05.1.3	Cocoa-based spreads, including fillings	3000	1000	1000 Note 113
05.1.4	Cocoa and chocolate products	3000	500	500 Note 113
05.3	Chewing gum	10000	5000	5000 Note 113
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit(and sweet sauces	1000	500	500 Note 113
06.3	Breakfast cereals, including rolled oats	1000	1200	1000 Note 119
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	1000	350	350 Note 113
07.1	Bread and ordinary bakery wares	4000	1000	1000 Note 113
10.4	Egg-based desserts (e.g. custard)	1000	350	350 Note 113
12.2.2	Seasonings and condiments	2000	2000	2000 Note 119
12.4	Mustards	350	350	350 Note 119
12.5	Soups and broths	1200	110	110 Note 113
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.4 and 05.1.3	350	350	350 Note 119
14.1.4	Water-based flavoured drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks	600	600	600 Note 119
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	600	600	600 Note 119
15.0	Ready-to-eat savouries	500	350	500 Note 119

The CCC requests the inclusion of the following provision at Step 3 in the GSFA for INS 951 Aspartame:

Food Cat No.	Food Category	Max Level	Step	Comments
6.8.1	Soy-based beverages	1500mg/kg	3	Aspartame adds sweetness to improve the flavor of soy-based beverages without adding calories. The amount requested is needed to achieve the appropriate technical effect.

The CCC requests the inclusion of the following provision at Step 3 in the GSFA for INS 954 Saccharins:

Food Cat No.	Food Category	Max Level	Step	Comments
14.1.3.4	Concentrates for vegetable nectar	80 mg/kg	3	Saccharins sweeten and improve the taste of fruit nectars without adding calories. The amount requested is needed to achieve the appropriate technical effect.

The CCC requests the inclusion of the following provision at Step 3 in the GSFA for INS 955 Sucralose:

Food Cat No.	Food Category	Max Level	Step	Comments
01.5.2	Milk and cream powder analogues	580 mg/kg	3	Sucralose sweetens milk and cream powder analogues without added carbohydrates and calories. Carbohydrates added to such products may result in browning reactions, impairing appearance and the value of proteins while sucralose remains inert. The CCFA has agreed that intense sweeteners may be used in this food category. Sucralose is used in this category in Japan. Based on the Japanese usage standard, CCC requests a maximum level of 580 mg/kg for sucralose in this category.

The CCC requests the inclusion of the following provisions at Step 3 in the GSFA for INS 961 Neotame:

Food Cat No.	Food Category	Max Level	Step	Comments
14.1.3.1	Fruit nectars	65 mg/kg	3	Neotame sweetens, improving the taste of fruit nectars without adding calories. The amount requested is needed to achieve the appropriate technical effect.
14.1.3.3	Concentrates for fruit nectars	65 mg/kg	3	Neotame sweetens, improving the taste of fruit nectars without adding calories. The amount requested is needed to achieve the appropriate technical effect.

International Chewing Gum Association

Background for a proposed revision of the provision for use of aspartame-acesulfame salt (INS 962) in food category 5.3 Chewing gum (at step 3)

ICGA submits the need to introduce a revised use level at step 3 for aspartame-acesulfame salt (INS 962) in food category 05.3 Chewing gum of 5.000 mg/kg, expressed on an acesulfame potassium basis.

The ICGA submits further that more generally any draft use levels (i.e. pending provisions) currently in the step process for aspartame-acesulfame salt may be replaced with revised use levels of aspartame-acesulfame salt to be provided by the food industry and introduce them at Step 3 into the GSFA Table 1 and 2, in order to address the appropriate reporting basis with which the use levels of aspartame-acesulfame salt in these food categories are expressed and allow consistency thoughout all provisions of aspartame-acesulfame salt (especially between the adopted provisions and those in the step process) and would be fully align all the provisions with earlier decisions the Committee, especially the one it took at its 41st session[10] when it adopted the new Note 113 and Note 119 and introduced them throughout the GSFA without a proper decision on the pending provisions which has not been finalised since then.

In the case of food category 05.3 chewing gum, the proposed revised use level of aspartame-acesulfame salt is important because it reflects previous deicisions of the Committee and the level shall be expressed on an acesulfame potassium equivalent basis, i.e. with GSFA Note 113 added to the provision.

Rationale for a proposed revised provision for use of aspartame-acesulfame salt (INS 962) in food category 5.3 Chewing gum

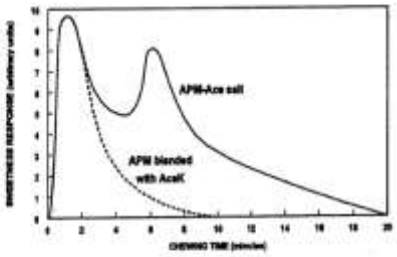
It should be noted that Table 2 of the on-line Codex GSFA already includes a Codex adopted level of use for acesulfame potassium at 5.000 mg/kg in 05.3 Chewing gum, adopted in 2007 as an international Codex standard. It should also be noted that Table 2 of the on-line Codex GSFA already includes a Codex adopted level of the use for Aspartame at 10.000 mg/kg in 05.3 Chewing gum, adopted in 2007 as an international Codex standard[11]. More generally only food categories with adopted Codex levels for aspartame and acesulfame potassium should be considered for a use of aspartame-acesulfame salt.

[10] See ALINORM 09/32/12, March 2009, Para. 95 at http://www.codexalimentarius.org/download/report/721/al32_12e.pdf

[11] See http://www.codexalimentarius.net/gsfaonline/foods/details.html?id=97&d-3586470-o=2&d-3586470-s=2

The full rationale for making this change as soon as the forthcoming 45th CCFA session is as stated in the Annex I of this letter and is presented according to the rules of "*Procedures for consideration of the entry and review of food additives provisions in the General Standard for Food Additives*"[12]. We trust that, in doing so, it will result in a swift discussion and adoption of that revised provision in chewing gum by Codex member countries.

Please find below a summary of the ICGA revised proposal for aspartame-acesulfame salt (INS 962) in 05.3 Chewing gum in the following table:

Food Category	Level (mg/kg)	Note(s)	Step	Technical Justification and Safety aspects	Recommendation to 45th CCFA session
05.3 Chewing gum	5000	113	3	Technological Justification and Needs: In chewing gum, it is highly important–that during chewing the taste is preserved as long as possible. A longer lasting sweetness is an essential condition for this. Combining the two sweeteners into one salt offers a unique synergistic effect of sweetness properties. In chewing gum it is highly important, that during chewing the sweetness release is balanced and preserved as long as possible, and using the salt helps achieve this. Aspartame-acesulfame salt does not have to be encapsulated, but already leads to a prolonged sweetness by itself. On top of that, use of the aspartame-acesulfame salt results in an extra sweetness boost after a few minutes of chewing, which leads to better tasting chewing gum for the consumer, as shown in the graph below based on blind tasting with consumer panels. Surprisingly, however, APM-Ace provides both a prolonged sweetness release and a distinct second boost to the sweetness profile. This is achieved simply by mixing the aspartame-acesulfame into the gum like any conventional ingredient. There is no need to resort to encapsulation. **Figure II.2.4(6)** gives an impression of this effect.  **Figure II.2.4(6). Impression of the sweetness release profile of chewing gum sweetened with aspartame-acesulfame compared with a gum containing an equimolar amount of a blend of aspartame with acesulfame-K.** Furthermore, it should be also noted that Aspartame-acesulfame salt is more stable to decomposition under similar storage conditions than mixtures of individual sweeteners when kept in a powdered form and this is useful for the food safety and to achieve high quality good manufacturing practices. Last but not least, because of its rapid solubility and low hygroscopic level, aspartame-acesulfame salt is not as degradable in dry or low moisture preparations (such as chewing gum) as other individual sweeteners and therefore plays a role in keeping the taste and flavour characteristics of chewing gum, which is a quite convenient characteristic in some remote areas, where chewing gum may have a longer on-shelf life before being consumed. Safety Use Level: Assuming the following conservative hypotheses (i.e. which are de facto overestimating the expected intake) usually admitted for chewing gum that: - all sugar-free chewing gums are sweetened with aspartame-acesulfame salt (or a consumer will eat always the same kind of chewing gum which contains acesulfame-aspartame salt as sweetener); - the level present in chewing gum is always the maximum permitted use level to be approved by Codex (i.e. 11 350 mg/kg expressed as salt = 5000 mg/kg expressed as Acesulfame potassium equivalent = 7264 mg/kg expressed as aspartame equivalent); - all aspartame-acesulfame salt present in the chewing gum is swallowed and then ingested by the body;	Revised use level to be introduced into Table 2 (and Table 1) of GSFA at Step 3 and proposed for further comments after 45th CCFA

[12] See Codex Procedural Manual, 20th edition, pages 55-61 (English version) available at http://www.codexalimentarius.org/procedures-strategies/procedural-manual/en/

Food Category	Level (mg/kg)	Note(s)	Step	Technical Justification and Safety aspects	Recommendation to 45th CCFA session
				- chewing gum daily consumption on a life-long basis is as high as 3g per day (heavy user); - an average person weighs 60 kg during their lifetime; and, - based on JECFA's ADIs for Aspartame (40 mg/kg body weight/day) and for Acesulfame potassium (15 mg/kg body weight/day), the estimated daily intake of aspartame and acesulfame potassium due to chewing gum consumption would be respectively 0,91% of the ADI aspartam$_e$ and 1,66% of the ADI Acesulfame potassium. These levels simply show that chewing gum daily intake is clearly not a main source of exposure to these intense sweeteners at the proposed level for aspartame-acesulfame salt of 5000 mg/kg, expressed as acesulfame potassium equivalent level. International harmonization of rules and ensuring fair practices in food trade It should be noted that aspartame-acesulfame salt is already authorised by several countries in the world for its use in chewing gum products and other confectionery at least in the 27 countries members of the European Union, the United States of America, Russia, Turkey and Australia-New Zealand. Therefore, ICGA submits that the use of aspartame-acesulfame salt in chewing gum at the proposed level of 5000 mg/kg expressed ona an acesulfame potassium basis is technologically justified, safe and fully in line with the dual mandate of Codex.	

Next steps

ICGA would suggest that all Codex members and interested international organisations are given an opportunity to discuss this revised proposed provision in chewing gum during the forthcoming 45th CCFA session under agenda item 5f). If agreeable by the Chairs of the Committee and of the pre-session physical working group, we request that preliminary discussions be held during the pre-session physical working group on GSFA in order to provide further recommendations to CCFA45.

International Council of Grocery Manufacturers Associations

According to Section II: Elaboration of Codex texts – Criteria for the Establishment of Work Priorities (a) Diversification of national legislations and apparent resultant or potential impediments to international trade, work can be prioritized relative to standards development. Diverse national legislation on aspartame-acesulfame (INS 962) presents actual impediments to international trade. Trade barriers for aspartame-acesulfame salt in for example gums have necessitated alternative formulations that are not optimal. Thus, ICGMA requests that the following new provisions be considered for inclusion at Step 3, and receive priority:

05.1.2 Cocoa mixes (syrups):	350 mg/kg (Note 97*, Note 113**)
05.1.3 Cocoa-based spreads, including fillings:	1,000 mg/kg (Note 113)
05.1.4 Cocoa and chocolate products:	500 mg/kg (Note 113)
05.2.1 Hard Candy	500 mg/kg (Note 113)
05.2.2 Soft Candy	1,000 mg/kg (Note 113)
05.2.3 Nougats and marzipans	1,000 mg/kg (Note 113)
05.3 Chewing gum	5,000 mg/kg (Note 113)
05.4 Decorations (e.g., for fine bakery wares), toppings (nonfruit) and sweet sauces	500 mg/kg (Note 113)

* **Note 97:** In the finished product/final cocoa and chocolate product.

** **Note 113**: Use level reported as acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68.)

Technological Justification

Sweeteners have been identified as technologically justified for use in the above food categories. (39th CCFA, CRD1 Annex V)

The combination of aspartame and acesulfame salts into one salt, i.e., aspartame-acesulfame, offers a unique synergistic effect of sweetness properties resulting in a longer lasting sweetness. Aspartame-acesulfame salt is more stable to decomposition under similar storage conditions than mixtures of individual sweeteners when kept in powdered form and this is useful for food safety and to achieve high quality good manufacturing practices. Due to its rapid

solubility and low hygroscopic level, aspartame-acesulfame salt is not as degradable in dry or low moisture preparations (such as chewing gum) as other individual sweeteners and, therefore, play a role in keeping the taste and flavor characteristics of chewing gum.

International Sweeteners Association

The ISA would like to submit the following proposals for new additive provisions of the GSFA, in line with the Procedure for consideration of the entry and review of food additive provisions in the GSFA.

1. Aspartame-acesulfame salt

The ISA would like to submit the following comments for the use of aspartame-acesulfame salt (INS 962) in the General Standard for Food Additives.

The ISA would like to propose that the CCFA discontinue any pending provisions in the GSFA relative to the use of these particular sweeteners in these food categories.

Aspartame-acesulfame salt provides a novel delivery vehicle for the sweeteners aspartame and acesulfame. As it is a single molecule comprising the constituent sweeteners, it provides unique benefits to food and beverage manufacturers.

For every food category of the GSFA listed below, both aspartame (INS 951) and acesulfame K (INS 950) are already approved and the technological need for use in the categories has already been established. The technological need for the use of the individual sweeteners in these categories applies also to the use of aspartame-acesulfame salt. The adoption of aspartame-acesulfame salt will offer food and beverage manufacturers more flexibility in process and handling while applying these same constituent sweeteners

For all the adopted provisions for aspartame and acesulfame K, the following notes accompany the maximum use levels agreed by the Codex Commission:

- For acesulfame: Note 188 *Not to exceed the maximum use level for acesulfame potassium (INS 950) singly or in combination with aspartame-acesulfame salt (INS 962).*
- For aspartame: Note 191 *Not to exceed the maximum use level for aspartame (INS 951) singly or in combination with aspartame-acesulfame salt (INS 962).*

The Codex Committee's inclusion of these notes when adopting provisions for aspartame and acesulfame K clearly shows that the intention was to also allow the use of aspartame-acesulfame salt in these categories.

On this basis, the ISA would like to submit the following provisions for the use of aspartame-acesulfame salt in the GSFA:

Food Category Number	Food Category	Max Level (mg/kg)	Step	Additional justification
01.3.2	Beverage Whiteners	2000 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
01.4.4	Cream Analogues	1000 *Note 119*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
01.5.2	Milk and Cream Powder Analogues	1000 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	1000 *Note 119*	3	
0.3	Edible ices, including sherbet and sorbet	1000 *Note 119*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
04.1.2.1	Frozen Fruit	500 *Note 113*	3	
04.1.2.2	Dried Fruit	500 *Note 113*	3	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	1000 *Note 119*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
04.1.2.7	Candied fruit	500 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
04.1.2.10	Fermented fruit products	350 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
04.1.2.11	Fruit fillings for pastries	350 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12

Food Category Number	Food Category	Max Level (mg/kg)	Step	Additional justification
04.1.2.12	Cooked Fruit	500 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	350 *Note 113* *Note 97*	3	
05.1.2	Cocoa mixes (syrups)	350 *Note 113* *Note 97*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
05.1.3	Cocoa-based spreads, including fillings	1000 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
05.1.4	Cocoa and chocolate products	500 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
05.2.1	Hard Candy	500 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
05.2.2	Soft Candy	1000 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
05.2.3	Nougats and marzipans	1000 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
05.3	Chewing Gum	5000 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12. Aspartame-acesulfame salt provides an improved stability in finished chewing gum products avoiding the need to encapsulate sweeteners, saving the food manufacturer an additional process step. Aspartame-acesulfame salt forms a stronger bond with gum bases allowing for a longer lasting sweetness and flavour in finished products. ISA supports the detailed technological justification for this food category provided by ICGA.
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	500 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
06.3	Breakfast Cereals, including rolled oats	1000 *Note 119*	3	
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	350 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
07.1	Bread and ordinary bakery wares	1000 *Note 113*	3	
10.4	Egg-based desserts (e.g., custard)	350 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	1000 *Note 113* *Note 159*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
14.1.3.2	Vegetable Nectar	350 *Note 113*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
14.1.3.4	Concentrates for vegetable nectar	350 *Note 113* *Note 127*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	600 *Note 119*	3	Food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	600 *Note 119* *Note 160*	3	

Note 97 *In the finished product/final cocoa and chocolate products*

Note 113 *Use level reported as acesulfame potassium equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.44). Combined use of aspartame-acesulfame salt with individual acesulfame potassium or aspartame should not exceed the individual maximum levels for acesulfame potassium or aspartame (the reported maximum level can be converted to aspartame equivalents by dividing by 0.68).*

Note 119 *Use level reported as aspartame equivalents (the reported maximum level can be converted to an aspartame-acesulfame salt basis by dividing by 0.64). Combined use of aspartame-acesulfame salt with individual aspartame or acesulfame potassium should not exceed the individual maximum levels for aspartame or acesulfame potassium (the reported maximum level can be converted to acesulfame potassium equivalents by multiplying by 0.68).* **Note 159** *For use in pancake syrup and maple syrup only.* **Note 127** *As served to the consumer* **Note 160** *For use in ready-to-drink products and pre-mixes for ready-to-drink products only* **Note 188** *Not to exceed the maximum use level for acesulfame potassium (INS 950) singly or in combination with aspartame-acesulfame salt (INS 962).* **Note 191** *Not to exceed the maximum use level for aspartame (INS 951) singly or in combination with aspartame-acesulfame salt (INS 962).*

In line with section 3.2 of the preamble of the GSFA, the ISA would present the following justification for the use of aspartame-acesulfame salt, as follows:

Aspartame-acesulfame salt is used as a high intensity sweetener in foods and beverages to provide the consumer with lower calorie sweet-tasting alternatives to sugar-sweetened foodstuffs.

Aspartame-acesulfame salt has been evaluated by JECFA and has been approved as safe. According to JECFA, *"The ADIs for aspartame (0-40 mg/kg bw) established at the 25th JECFA (1981) and for acesulfame K (0-15 mg/kg bw) established at the 37th JECFA (1990) cover the aspartame and acesulfame moieties of the salt".* The JECFA food additive specification for aspartame-acesulfame salt is included in ***Annex I.***

The use of aspartame- acesulfame salt does not mislead the consumer as the presence must always be indicated in the list of ingredients.

The technological function is 'sweetener'.

Use of aspartame- acesulfame salt provides consumers with lower calorie foods and beverages which are helpful to consumers who wish to manage their weight. High intensity sweeteners are also suitable for diabetics as they have no impact on insulin or blood sugar levels.

2. Sucralose

The ISA would like to submit the following provision for the use of sucralose (INS 955):

Food Category Number	Food Category	Max Level (mg/kg)	Step	Additional justification
01.5.2	Milk and cream powder analogues	400	3	Sucralose allows for the manufacture of pre-sweetened milk and cream powder analogues with no added carbohydrates, no added flavours and no other added foods. Addition of carbohydrates to such products may result in browning reactions with impaired appearance of the product and impaired value of proteins while sucralose remains inert. This is a food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12. Several other sweeteners are already approved for use in this category in the GSFA, including aspartame and acesulfame K. Sucralose is used in food applications of this category in Japan. Based on the Japanese usage standard, ISA would request a maximum level of 400mg/kg for sucralose in this category.

In line with section 3.2 of the preamble of the GSFA, the ISA would present the following justification for the use of sucralose, as follows:

Sucralose is used as a high intensity sweetener in foods and beverages to provide the consumer with lower calorie sweet-tasting alternatives to sugar-sweetened foodstuffs

Sucralose has been evaluated by JECFA and has been approved as safe. An ADI of 0-15 mg/kg bw was established at the 37th JECFA (1990). The JECFA food additive specification for sucralose is included in ***Annex II.***

The use of sucralose salt does not mislead the consumer as the presence must always be indicated in the list of ingredients.

The technological function is 'sweetener'.

Use of sucralose provides consumers with lower calorie foods and beverages which are helpful to consumers who wish to manage their weight. High intensity sweeteners are also suitable for diabetics as they have no impact on insulin or blood sugar levels.

3. Neotame

The ISA would like to submit the following provisions for the use of neotame (INS 961):

Food Category Number	Food Category	Max Level (mg/kg)	Step	Additional justification
14.1.3.1	Fruit nectar	65	3	This is a food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12. Products within these application categories are typically subjected to a heat treatment (pasteurization). Neotame's robust stability under elevated temperatures allows for extra flexibility in processing - where food manufacturers may otherwise have to add more sweetener later in the process to avoid loss of sweetness.
14.1.3.3	Concentrates for fruit nectar	65	3	This is a food category in which the use of sweeteners is technologically justified –Appendix V, CRD 1, 39th CCFA, Alinorm 07/30/12. Products within these application categories are typically subjected to a heat treatment (pasteurization). Neotame's robust stability under elevated temperatures allows for extra flexibility in processing - where food manufacturers may otherwise have to add more sweetener later in the process to avoid loss of sweetness.

In line with section 3.2 of the preamble of the GSFA, the ISA would present the following justification for the use of neotame, as follows:

Neotame is used as a high intensity sweetener in foods and beverages to provide the consumer with lower calorie sweet-tasting alternatives to sugar-sweetened foodstuffs

Neotame has been evaluated by JECFA and has been approved as safe. An ADI of 0-2 mg/kg bw was established at the 61st JECFA (2003). The JECFA food additive specification for neotame is included in ***Annex III.***

The use of neotame does not mislead the consumer as the presence must always be indicated in the list of ingredients.

The technological function is 'sweetener'.

Use of neotame provides consumers with lower calorie foods and beverages which are helpful to consumers who wish to manage their weight. High intensity sweeteners are also suitable for diabetics as they have no impact on insulin or blood sugar levels.