

# CODEx ALIMENTARIUS COMMISSION



**Food and Agriculture  
Organization of  
the United Nations**



**World Health  
Organization**

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Agenda Item 5e

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEx COMMITTEE ON FOOD ADDITIVES

Forty-eighth Session

Xi'an, China, 14-18 March 2016

### PROPOSALS FOR NEW AND/OR REVISION OF FOOD ADDITIVE PROVISIONS

Proposal from Japan

Annex I

#### FORM FOR THE SUBMISSION OF PROPOSALS FOR NEW AND/OR REVISION OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA

*In completing this form, only brief information is required. However, responsive information is required for each field. The form may be retyped if more space is needed under any one heading provided that the general format is maintained. A separate table should be completed for each food additive.*

<b>THE PROPOSAL IS SUBMITTED BY:</b>		Japan	
<b>IDENTITY OF THE FOOD ADDITIVE:</b>			
<b>Name of the Additive</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Advantame	
<b>INS Number</b>		969	
<b>Functional Class</b> <i>As listed in Class Names and the International Numbering System (INS) - CAC/GL 36-1989</i>		Sweetener Flavour enhancer	
<b>PROPOSED USE(S) OF THE FOOD ADDITIVE:</b> <i>The rows below may be copied as many times as needed.</i>		The proposal for <input checked="" type="checkbox"/> a new provision; or <input type="checkbox"/> revising an existing provision	
<b>Food Category No.</b>	<b>Food Category Name</b>	<b>Maximum Use Level (1)</b>	<b>Comments</b>
01.1.2	Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks)	6 mg/kg	Besides adding sweetness, advantame can enhance flavor of milk-added products of this food category.  Maximum Use Level is set based on sweetener function.
01.3.2	Beverage whiteners	60 mg/kg	
01.4.4	Cream analogues	10 mg/kg	
01.5.2	Milk and cream powder analogues	20 mg/kg	
01.6.1	Unripened cheese	10 mg/kg	
01.6.5	Cheese analogues	10 mg/kg	
01.7	Dairy-based desserts (e.g., pudding, fruit or flavoured yoghurt)	10 mg/kg	Advantame can be used in this category because it is highly soluble in fat in comparison with other sweeteners.
02.3	Fat emulsions mainly of type oil-in-water, including mixed and/or flavoured products based on fat emulsions	10 mg/kg	
02.4	Fat-based desserts excluding dairy-based dessert products of food category	10 mg/kg	

	01.7		Maximum Use Level is set based on sweetener function..
03	Edible ices, including sherbet and sorbet	10 mg/kg	Besides adding sweetness, advantame can enhance flavor of fruit and/or milk-added products of this food category. Maximum Use Level is set based on sweetener function.
04.1.2.1	Frozen fruit	20 mg/kg	Besides adding sweetness, advantame can enhance flavor of fruit of this food category.  Maximum Use Level is set based on sweetener function.
04.1.2.2	Dried fruit	20 mg/kg	
04.1.2.3	Fruit in vinegar, oil, or brine	3 mg/kg	
04.1.2.4	Canned or bottled (pasteurized) fruit	10 mg/kg	
04.1.2.5	Jams, jellies, marmelades	10 mg/kg	
04.1.2.6	Fruit-based spreads (e.g., chutney) excluding products of food category 04.1.2.5	10 mg/kg	
04.1.2.7	Candied fruit	20 mg/kg	
04.1.2.8	Fruit preparations, including pulp, purees, fruit toppings and coconut milk	10 mg/kg	
04.1.2.9	Fruit-based desserts, including fruit-flavoured water-based desserts	10 mg/kg	
04.1.2.10	Fermented fruit products	10 mg/kg	
04.1.2.11	Fruit fillings for pastries	10 mg/kg	
04.1.2.12	Cooked fruit	10 mg/kg	
04.2.2.1	Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	10 mg/kg	
04.2.2.2	Dried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	10 mg/kg	
04.2.2.3	Vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds in vinegar, oil, brine, or soybean sauce	3 mg/kg	Note 144 :For use in sweet and sour products only. Besides adding sweetness, advantame can enhance flavor of fruit of this food category. Maximum Use Level is set based on sweetener function.
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	10 mg/kg	Besides adding sweetness, Advantame can enhance flavor of fruit of this food category. Maximum Use Level is set based on sweetener function.
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)	10 mg/kg	
04.2.2.6	Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed pulps and preparations (e.g., vegetable desserts and sauces, candied vegetables) other than food category 04.2.2.5	10 mg/kg	

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	25 mg/kg	
04.2.2.8	Cooked or fried vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds	10 mg/kg	
05.1.1	Cocoa mixes (powders) and cocoa mass/cake	30 mg/kg	Note 97 :On the final cocoa and chocolate product basis. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
05.1.2	Cocoa mixes (syrops)	10 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
05.1.3	Cocoa-based spreads, including fillings	30 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
05.1.4	Cocoa and chocolate products	30 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
05.1.5	Imitation chocolate, chocolate substitute products	30 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
05.2.1	Hard candy	30 mg/kg	New note :Except for use in microsweets and breath freshening mints at 100 mg/kg.
05.2.2	Soft candy	30 mg/kg	New note :Except for use in microsweets and breath freshening mints at 100 mg/kg. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
05.2.3	Nougats and marzipans	30 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.

05.3	Chewing gum	100 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
05.4	Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces	10 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
06.3	Breakfast cereals, including rolled oats	10 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
06.5	Cereal and starch based desserts (e.g., rice pudding, tapioca pudding)	10 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
07.1.5	Steamed breads and buns	10 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
07.2	Fine bakery wares (sweet, salty, savoury) and mixes	17 mg/kg	Note 165 :For use in products for special nutritional use only. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
09.2	Processed fish and fish products, including mollusks, crustaceans, and echinoderms	3 mg/kg	Note 144 :For use in sweet and sour products only. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
09.3	Semi-preserved fish and fish products, including mollusks, crustaceans, and echinoderms	3 mg/kg	Note 144 :For use in sweet and sour products only. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
09.4	Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans, and echinoderms	3 mg/kg	Note 144 :For use in sweet and sour products only. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.

10.4	Egg-based desserts (e.g., custard)	10 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
11.4	Other sugars and syrups (e.g., xylose, maple syrup, sugar toppings)	30 mg/kg	Note 159 : For use in pancake syrup and maple syrup only. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
11.6	Table-top sweeteners, including those containing high-intensity sweeteners	GMP	Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
12.2.2	Seasonings and condiments	20 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
12.3	Vinegars	30 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
12.4	Mustards	3.5 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
12.5	Soups and broths	12 mg/kg	Note XS117 : Excluding products conforming to the Codex Standard for Bouillons and Consommés (CODEX STAN 117-1981). Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
12.6	Sauces and like products	3.5 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
12.7	Salads (e.g., macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based spreads of food categories 04.2.2.5 and 05.1.3	3.5 mg/kg	Note :166 For use in milk-based sandwich spreads only. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted

			provision for aspartame.
13.3	Dietetic foods intended for special medical purposes (excluding products of food category 13.1)	10 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
13.4	Dietetic formulae for slimming purposes and weight reduction	8 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
13.5	Dietetic foods (e.g., supplementary foods for dietary use) excluding products of food categories 13.1 - 13.4 and 13.6	10 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
13.6	Food supplements	55 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
14.1.3.1	Fruit nectar	6 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
14.1.3.2	Vegetable nectar	6 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
14.1.3.3	Concentrates for fruit nectar	6 mg/kg	Note 127 :On the served to the consumer basis. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
14.1.3.4	Concentrates for vegetable nectar	6 mg/kg	Note 127 :On the served to the consumer basis. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
14.1.4	Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks	6 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	6 mg/kg	Note 160 : For use in ready-to-drink products and pre-mixes for ready-to-drink

			products only. Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
14.2.7	Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low alcoholic refreshers)	6 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
15.0	Ready-to-eat savouries	5 mg/kg	Maximum Use Level is set based on sweetener function. Technological justification corresponds to adapted provision for aspartame.
<b>EVALUATION BY JECFA:</b>			
<b>Evaluation by JECFA</b> <i>Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or "not specified"); specifications monograph).</i>		Safety evaluation was conducted in the seventy-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives. An ADI of 0-5 mg/kg bw was set. Specification monograph was published in the 80 <sup>th</sup> JECFA meeting report.	
<b>JUSTIFICATION:</b>			
<b>Justification for use and technological need</b> <i>Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).</i>		<p>The intended use of Advantame is to replace caloric sugars (sucrose, glucose, fructose, etc.) in the categories of foods in which high-intensity sweeteners are permitted by the GSFA.</p> <p>The actual use levels that will be incorporated to calorie-reduced foods will vary between individual manufacturers and products, but will be covered by current Good Manufacturing Practices (GMP) and/or the maximum permitted usage levels which will be derived on a sweetness basis of aspartame within the individual food categories.</p> <p>Furthermore advantame is a flavor enhancer, enhancing many flavors such as dairy, fruit, citrus, mint, etc. and can be used to extend chew time in chewing gum. Advantame is also a tool in masking off-tastes of functional ingredients, such as added proteins, vitamins, minerals, etc.</p> <p>In addition, advantame can be used as a sweetener for Fat-based products, fat emulsions and other high fat content products because it is highly soluble in fat in comparison with other sweeteners.</p>	
<b>Safe use of additive: Dietary intake assessment</b> <i>(as appropriate)</i>		<p><i>Table 3 additive:</i></p> <p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No <i>(Please provide information on dietary intake assessment below)</i></p> <p>FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS STATISTICS DIVISION (FAOSTAT) database includes estimates for all kind of sweetener supply for all countries and regions (WHO, 2011). Assuming, as a worst case scenario, that Advantame would replace all sugar supply, intake values of Advantame can be estimated; however, such intake estimates would be highly conservative since it is unlikely that Advantame would entirely replace sugar supply and the consumption of sweeteners should be smaller than the sweeteners supply. Considering that Advantame is approximately 20,000 times as sweet as sucrose, per capita intake of Advantame of up to 8.15 mg/day (0.136 mg/kg body weight/day) is estimated based on commodity sweetener.</p>	
		Commodity	Predicted intakes of Advantame (mg/kg body

	Sweetener (g/capita/day)	weight)	
		mg/capita/day	mg/kg BW/day
Africa	45	2.25	0.038
Northern America	161	8.05	0.134
Southern America	107	5.35	0.089
Asia	47	2.35	0.039
Europe	111	5.55	0.093
Australia & New Zealand	130	6.50	0.108
<p>Commodity Sweetener is the amount of monosaccharides (glucose and fructose) and disaccharides (sucrose and saccharose) used for sweetening.</p> <p>Proposed maximum use levels of advantame are calculated from those of aspartame within corresponding food categories by dividing 100, as the sweetness of advantame is considered to be 100 times higher than that of aspartame. JECFA has established an ADI of 0 – 5 mg/kg bw for advantame. Considering the above, even if advantame would replace all use of Commodity Sweeteners, intake of advantame does not exceed upper bound of the ADI of advantame, and the use of advantame is of negligible safety concern.</p>			
<b>Justification that the use does not mislead consumer</b>	<p>An increase of numbers of sweeteners permitted by the GSFA would be advantageous for the consumers who are forced to eat Sugar-Free, Low-Calorie or Sugarless foods only due to their physical problems.</p> <p>By properly displayed on the label in accordance with the law in each regions, consumers easily understand that advantame is contained in foods and the product has a feature that is different from the products that were made only with sugar.</p>		

(<sup>1</sup>) Proposed maximum use levels of advantame are derived on a sweetness basis of aspartame within the corresponding food categories.