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New Food Additives Allowed - Cyclamate and Steviolglycoside

Report Categories:
Sanitary/Phytosanitary/Food Safety

Approved By:
Rey Santella, Agricultural Attaché

Prepared By:
Sukanya Sirikeratikul, Marketing Specialist

Report Highlights:
TH2138: On December 3, 2012 the Thai Food and Drug Administration (FDA) notified the WTO of proposed changes to Thailand's rules relating to Cyclamate (G/SPS/N/THA/210) and Steviol glycoside (G/SPS/N/THA/211) as food additives. U.S. companies exporting these substances and food products containing Cyclamate and Steviol glycoside are encouraged to review the proposed maximum use levels. Under the proposed rules, Cyclamate and Steviol glycoside can be used as food additives (sweeteners or ingredients in processed foods). Thailand's sweetener imports in 2011 totaled nearly $140 million. Post estimates the market for consumer oriented products containing sweeteners to Thailand could reach $33 million by 2015.

General Information:
Thailand Proposes to Revise its Rules for Cyclamate and Steviol glycoside as Food Additives.

On December 3, 2012 the Thai Food and Drug Administration (FDA) notified the WTO of proposed changes to Thailand's rules governing the use of Cyclamate and Steviol glycoside as food additives (G/SPS/N/THA/209-211). The decision to revise its standards followed the joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluation, which determined acceptable daily intake (ADI) levels for cyclamic acid, its sodium or calcium salts, and Steviol glycoside. Hence, the Ministry of Public Health issued the following notifications.

1. *Ministry of Public Health Notification Regarding Prescribed Prohibited Food to be Produced, Imported or Sold (G/SPS/N/THA/209)*

The proposal revises and amends Ministry of Public Health Notification (No.292) B.E.2548, which allows cyclamic acid and its sodium or calcium salts and Steviol glycoside as food additives in food products. The regulation will still prohibit the production, import or sale of Stevia, which is known by its scientific name as "Stevia rebaudiana Bertoni."

2. *Ministry of Public Health Notification Regarding Food Additive (No.3): Cyclamate (G/SPS/N/THA/210)*

This proposal stipulates that the Thai FDA will follow CODEX's General Standard for Food Additives (GSFA) which establishes quality requirements, standards, and use requirements for cyclamic acid and its sodium or calcium salts in different food types.

3. *Ministry of Public Health (No…) B.E…RE: Food Additive (No.4): Steviol glycoside (G/SPS/N/THA/211)*

This proposal stipulates that the Thai FDA will follow Codex's General Standard for Food Additives (GSFA) which establishes quality requirements, standards, and use requirements for Steviol glycoside in different food types. Thai FDA's rules will differ from Codex's maximum levels in the following categories:

- Maximum level is set at 70 mg/kg for products containing milk as a major component (flavored type), either fermented or not (food category code 01.1.2) with the exception of products prohibited under the Ministry of Public Health Notification regarding cow milk and flavored milk;
- Maximum level is set at 100 mg/kg for soy milk (food category code 06.8.1);
- Maximum level is set at 115 mg/kg for flavored drinks (food category code 14.1.4), except those prohibited under the Ministry of Public Health Notification regarding electrolyte drinks; and
- Maximum level is at 1,100 mg/kg for chewing gum (food category code 05.3).

The following products are not permitted for use as sweeteners in Thailand: cow milk, flavored milk, jam, jelly and marmalade in sealed container, chocolate and electrolyte drinks. If approved, the new rules will allow for Cyclamate and Steviol glycoside to be used as sweeteners or ingredients in

processed foods. Please refer to the various notifications for specific details. Thailand's sweetener imports in 2011 totaled nearly $140 million. Post estimates the market for consumer oriented products containing sweeteners to Thailand could reach $33 million by 2015.

APPENDIX

Appendix I: Notification of the Ministry of Public Health (No…) B.E…. Re: Prescribed Prohibited Food to be Produced, Imported, or Sold

(Draft)
Notification of the Ministry of Public Health
(No…) B.E….
RE: Prescribed Prohibited Food to be Produced, Imported, or Sold
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Whereas it is appropriate to revise the Notification of the Ministry of Public Health RE: Prescribed Prohibited Food to be Produced, Imported, or Sold;

By virtue of the provisions of Section 5 and Section 6 (8) of the Foods Act B.E.2522 which is an act containing some provisions concerning the limitation of the rights and freedom of a person, which Section 29 combined with Section 33, Section 41, Section 43 and Section 45 of the Constitution of the Kingdom of Thailand prescribes to be permissible by virtue of a legislation, the Minister of Public Health issues a notification as follows:

1. The Notification of the Ministry of Public Health (No. 292) B.E.2548 RE: Prescribed Prohibited Food to be Produced, Imported, or Sold dated 15 November 2005 shall be repealed.

2. The following foods shall be prohibited from being produced, imported or sold:

2.1 Dulcin or also known by its chemical name as para-phenetolcarbamide used as sweetner.

2.2 AF_2 or in general name as Furylframide or in chemical name as 2-(2-furyl)-3-(5-nitro-2-furyl) acrylamide if used as food additive

2.3 Potassium bromate if used as food additive

2.4 Food with Dulcin, AF2, Potassium bromated or Cyclamic acid and its salts as food component except Cyclamic acid salt containing Sodium Cyclamate as food component.

2.5 Food with Daminozide or Succinic acid 2,2-dimethylhydrazide

2.6 Stevia or in scientific name as Stevia rebaudiana Bertoni and its products except for production, import or sale of

(1) Stevia leaf pursuant to the Notification of the Ministry of Public Health Re: Herbal Tea

(2) Steviol glycoside pursuant to the Notification of the Ministry of Public Health Re: Food Additive (No. 4): Steviol glycoside

(3) Stevia or its products used for production or such imported or sold for production of Steviol glycoside according to (2) above

(4) Stevia or its products produced for export

3. This notification shall come into force as from the day following date of its publication in the Government Gazette.

Given on this ……

Appendix II: Notification of the Ministry of Public Health (No…) B.E…. Re: Food Additive (No. 3): Cyclamate

(Draft)
Notification of the Ministry of Public Health
(No…) B.E….
RE: Food Additive (No. 3): Cyclamate

Whereas it is expedient to allow the use of Cyclamic acid and sodium or calcium salts of Cyclamic acid as food additives where the Joint FAO/WHO Expert Committee on Food Additives or JECFA has assessed and determined Acceptable Daily Intake: ADI;

By virtue of the provisions of Section 5 and Section 6(1)(2)(4)(5)(6)(7)(9) and (10) of the Foods Act B.E.2522 which is an act containing some provisions concerning the limitation of the rights and freedom of a person, which Section 29 combined with Section 33, Section 41, Section 43 and Section 45 of the Constitution of the Kingdom of Thailand prescribes to be permissible by virtue of a legislation, the Minister of Public Health issues a notification as follows:

1. The Notification of the Ministry of Public Health No. 113 (B.E.2531) Re: Sodium Cyclamate and Foods containing Sodium Cyclamate dated 7 March 1988 shall be repealed.

2. Cyclamate shall be considered as food additives.

3. Cyclamate shall refer to Cyclamic acid (Cyclohexylsulfamic acid [INS No. 952(i)]) and sodium or calcium salts of Cyclamic acid such as Sodium Cyclamate (Sodium cyclohexylsulfamate or Sodium cyclohexanesulfamate [CAS: 139-05-9, INS No. 952(iv)]) or Calcium Cyclamate (Calcium cyclohexylsulfamate or Calcium cyclohexanesulfamate [CAS: 139-06-0, INS No. 952(ii)]).

4. Production or import for sale of Cyclamate shall be in compliance with the Notification of the Ministry of Public Health (No.281) B.E.2547 RE: Food Additives dated 18 August 2004 except the observance of Clause 4 and Clause 6, this Notification shall be applicable.

5. Sodium Cyclamate shall bear quality or standard as follows:

Chemical name: Sodium cyclohexylsulfamate or Sodium cyclohexanesulfamate [CAS: 139-05-9, INS No. 952(iv)]

Formula: Sodium Cyclamate: $C_6H_{12}NNaO_3S$, molecular weight 201.22

Properties: colorless crystal powder or white crystal

Specification: Quantity not less than 98% and not exceeding 101% of dried weight

- Sodium; pass the test
- Crystallization: test by using 10 ml. of solution 10 parts in 100 added with Hydrochloric acid 1 ml, mix them well and then added with Barium chloride 1 ml to get clear solution and when being added with Sodium nitrite 1 ml, it will become white crystal.
- Weigh loss when dried: not exceeding 1.0% (105 degree Celsius, 1 hour)
- Purity: Cyclohexylamine not exceeding 10 mg/kg and Dicyclohexylamine not exceeding 1 mg/kg

Limit of foreign substance : Lead not exceeding 1 mg/kg

Packing and storage: kept in sealed container

Quality or standard: referred to JECFA Monograph (2004) or if such quality or standard is amended, as per the latest version

6. Calcium Cyclamate shall bear quality or standard as follows:

Chemical name: Calcium cyclohexylsulfamate **หรอ** Calcium cyclohexanesulfamate [CAS: 139-06-0, INS No. 952(ii)]

Formula: Calcium Cyclamate: $C_{12}H_{24}CaN_2O_6S_2 2H_2O$ molecular weight 432.57

Properties: Colorless crystal power or white crystal, approximately 30 times sweet compared with sucrose

Specification: Quantity not less than 98% and not exceeding 101% of dried weight

- Calcium; pass the test
- Crystallization: test by using 10 ml. of solution 10 parts in 100 added with Hydrochloric acid 1 ml, mix them well and then added with Barium chloride 1 ml to get clear solution and when being added with Sodium nitrite 1 ml, it will become white crystal
- Weigh loss when dried: not less than 6.0% and not exceeding 9.0%
- Purity: Cyclohexylamine not exceeding 10 mg/kg and Dicyclohexylamine not exceeding 1 mg/kg

Limit of foreign substance : Lead not exceeding 1 mg/kg

Packing and storage: kept in closed container

Quality or standard: referred to JECFA Monograph (2004) or if such quality or standard is amended, as per the latest version

7. The use of Cyclamate as sugar substitute shall be subject to the requirements based on food types and its quantity as specified in the schedule attached to this Notification only.

8. This notification shall come into force as from the day following date of its publication in the Government Gazette.

Given on this ……

Schedule of Requirements for use of Cyclamate attached to the Notification of the Ministry of Public Health (No…) B.E…RE: Food Additive (No.3): Cyclamate

No.	Name and functions in the food	Food category code	Food Type	Maximum quantity allowed (mg/kg) except specific quantity specified
1. (INS 952)	Cyclamate **Other names:** - Cyclamic acid, INS 952 (i) - Calcium Cyclamate, INS 952 (ii) - Sodium Cyclamate, INS 952 (iv) **Function:** - sweetener	01.1.2	Drinks containing milk as major component, either in fluid or powder form, either fermented or not but excluding flavored milk	250 calculated in Cyclamic acid
		01.7	Sweets containing milk as major component	250 calculated in Cyclamic acid
		02.4	Sweets containing fat as major component	250 calculated in Cyclamic acid
		03.0	Ice cream	250 calculated in Cyclamic acid
		04.1.2.4	Fruits processed by canning	1000 calculated in Cyclamic acid
		04.1.2.6	Products with fruits as major component used for baked product not including those under section 04.1.2.5	2000 calculated in Cyclamic acid
		04.1.2.8	Transformed fruits ready for cooking	250 calculated in Cyclamic acid
		04.1.2.9	Sweets containing fruits as major component	250 calculated in Cyclamic acid
		04.2.2.6	Vegetables, seaweed, nuts and crushed kernels	250 calculated in Cyclamic acid
		05.1.3	Products made of cocoa used for paste or filling of baked product not including chocolate	500 calculated in Cyclamic acid
		05.1.4	Cocoa and chocolate not including chocolate	500 calculated in Cyclamic acid

		05.1.5	Chocolate-like products	500 calculated in Cyclamic acid
		05.2	Candy, nougat and marzipan	500 calculated in Cyclamic acid for candy or small pastille with very sweet flavor or mint-flavored fresh breath pill acceptable up to 2,500 mg/kg
		05.3	Chewing gum	3000 calculated in Cyclamic acid
		05.4	Products used for decorating sweets	500 calculated in Cyclamic acid
		06.5	Sweets containing cereals and starch as major component	250 calculated in Cyclamic acid
		07.2	Pastry (sweet, salty, special flavor) and mixes	1600 calculated in Cyclamic acid for products used for special nutrition purpose
		10.4	Sweets containing egg as major component	250 calculated in Cyclamic acid
		11.4	Sugar and syrup used for topping or decorating purpose	500 calculated in Cyclamic acid used for pancake topping syrup or maple syrup only
		11.6	Sweetener	Proper amount calculated in Cyclamic acid
		12.6.1	Emulsion sauce	500 calculated in Cyclamic acid
		12.7	Salad and sandwich spreads	500 calculated in Cyclamic acid
		13.3	Medical food	400 calculated in Cyclamic acid
		13.4	Foods for weight controlled person	400 calculated in Cyclamic acid
		13.5	Foods of special nutrition purpose	400 calculated in Cyclamic acid
		13.6	Dietary supplement	1250 calculated in Cyclamic acid
		14.1.3.1	Nectar fruit juice	400 calculated in Cyclamic acid
		14.1.3.2	Nectar vegetable juice	400 calculated in Cyclamic acid
		14.1.3.3	Concentrate nectar fruit juice	400 calculated in Cyclamic acid in condition directly sold to the consumer
		14.1.3.4	Concentrate nectar vegetable juice	400 calculated in Cyclamic acid in condition directly sold to the consumer
		14.1.4	Flavored drinks not including electrolyte drinks	350 calculated in Cyclamic acid in condition directly sold to the consumer
		14.2.7	Flavored alcohol drinks	250 calculated in Cyclamic acid

Appendix III: Notification of the Ministry of Public Health (No…) B.E…. Re: Food Additive (No. 4): Steviol glycosides

(Draft)
Notification of the Ministry of Public Health
(No…) B.E….
RE: Food Additive (No. 4): Steviol glycosides

Whereas it is appropriate to allow the use of Steviol glycosides consisting of Stevioside, Rebaudioside A, Rebaudioside B, Rebaudioside C, Rebaudioside D, Rebaudioside F, Dulcoside A, Rubusoside and Steviolbioside as food additives where the Joint FAO/WHO Expert Committee on Food Additives or JECFA has assessed and determined Acceptable Daily Intake: ADI;

By virtue of the provisions of Section 5 and Section 6(1)(2)(4)(5)(6)(7)(9) and (10) of the Foods Act B.E.2522 which is an act containing some provisions concerning the limitation of the rights and freedom of a person, which Section 29 combined with Section 33, Section 41, Section 43 and Section 45 of the Constitution of the Kingdom of Thailand prescribes to be permissible by virtue of a legislation, the Minister of Public Health issues a notification as follows:

1. The Notification of the Ministry of Public Health (No. 262) B.E.2545 RE: Stevioside and Food containing Stevioside dated 26 September 2002 shall be repealed.

2. Steviol glycosides shall be considered as food additives.

3. Steviol glycosides shall refer to pure extracts from Stevia rebaudiana Bertoni consisting of

Stevioside, Rebaudioside A, Rebaudioside B, Rebaudioside C, Rebaudioside D, Rebaudioside F, Dulcoside A, Rubusoside and Steviolbioside.

4. Production or import for sale of Steviol glycosides shall be in compliance with the Notification of the Ministry of Public Health (No.281) B.E.2547 RE: Food Additives dated 18 August 2004 except the observance of Clause 4 and Clause 6, this Notification shall be applicable.

5. Steviol glycosides shall bear quality or standard as follows:

Chemical name:

Stevioside: 13-[(2-O-β-D-glucopyranosyl-β-D-glucopyranosyl)oxy]kaur-16-en-18-oic acid or β-D-glucopyranosyl ester [CAS : 57817-89-7, INS No. 960]

Rebaudioside A: 13-[(2-O-β-D-glucopyranosyl-3-O-β-Dglucopyranosyl-β-D-glucopyranosyl)oxy] kaur-16-en-18-oic acid or β-D-glucopyranosyl ester [CAS: 58543-16-1, INS No. 960]

Formula: Stevioside: $C_{38}H_{60}O_{18}$ molecular weight 804.88

Rebaudioside A: $C_{44}H_{70}O_{23}$ molecular weight 967.03

Properties: white or pale yellow powder, odorless or unique odor, 200-300 times sweeter than sugar

Specification: contain total substances in Steviol glycosides group not less than 95% of dried weight

- water soluble
- pH 4.5-7.0 of solution 1 part in 100
- non-soluble items: passed the test
- purity: Ash not exceeding 1%

Weight loss when dried: not exceeding 6.0%

Residue solvent not exceeding 200 mg/kg (methanol) or not exceeding 5000 mg/kg (ethanol)

Limits for foreign substance: arsenic not exceeding 1 mg/kg and lead not exceeding 1 mg/kg

Packing and storage: kept in sealed container

Quality or standard: referred to JECFA Monograph (2010) or if such quality or standard is amended, as per the latest version

6. The use of Steviol glycosides as sweetener shall be subject to the requirements based on food types and its quantity as specified in the schedule attached to this Notification only.

7. The food producer or importer permitted under the Notification of the Ministry of Public Health (No.262) B.E. 2545 Re: Stevioside and Foods containing Stevioside dated 26 September 2002 shall properly register food recipe according to this Notification and the Notification of the Ministry of Public Health (No. 281) B.E.2547 RE: Food Additives dated 18 August 2004 within 1 year from the date this Notification has come into force.

Foods containing Stevioside used as food for weight controlled person according to the Notification of the Ministry of Public Health No. 121 (B.E.2536) RE: Foods for Weight Controlled Person dated 23 May 1989 shall be revised as to their details to be in compliance with this Notification within 1 year from the date this Notification has come into force.

8. This notification shall come into force as from the day following date of its publication in the Government Gazette.

Given on this ……

Schedule of Requirements for the use of Steviol glycosides attached to the Notification of the Ministry of Public Health (No…) B.E…RE: Food Additive (No.4): Steviol glycosides

No.	Name and functions in the food	Food category code	Food Type	Maximum quantity allowed (mg/kg) except specific quantity specified
1. (INS 960)	Steviol glycosides Other name: Steviol glycosides Function: - Sweetener	01.1.2	Drinks containing milk as major component, either in fluid or powder form (flavored), either fermented or not but excluding flavored milk	70 calculated in Steviol used for flavoring agent only
		01.5.2	Milk-like and cream power-like products	330 calculated in Steviol used for flavoring agent only
		01.7	Sweets containing milk as major component	330 calculated in Steviol
		02.4	Sweets containing fat as major component	330 calculated in Steviol
		03.0	Ice cream	270 calculated in Steviol
		04.1.2.3	Fruits in vinegar, oil, or brine	100 calculated in Steviol
		04.1.2.4	Fruits processed by canning	330 calculated in Steviol
		04.1.2.6	Products with fruits as major component used for baked product not including those under section 04.1.2.5	330 calculated in Steviol
		04.1.2.7	Fruits preserved in syrup	40 calculated in Steviol
		04.1.2.8	Transformed fruits ready for cooking	330 calculated in Steviol
		04.1.2.9	Sweets containing fruit as major component	350 calculated in Steviol
		04.1.2.10	Fermented fruits	115 calculated in Steviol
		04.1.2.11	Fillings for pastry made from fruits	330 calculated in Steviol
		04.1.2.12	Ready cooked fruits	40 calculated in Steviol
		04.2.2.2	Vegetables, seaweed, nuts and kernels in dried condition	40 calculated in Steviol
		04.2.2.3	Vegetables, seaweed in vinegar, oil, brine, or soy sauce	330 calculated in Steviol
		04.2.2.4	Vegetables, seaweed processed by canning	70 calculated in Steviol
		04.2.2.5	Vegetables, seaweed, nuts and kernels crushed or used for making pastry	330 calculated in Steviol
		04.2.2.6	Vegetables, seaweed, nuts and crushed kernels	165 calculated in Steviol
		04.2.2.7	Fermented vegetables, seaweed	200 calculated in Steviol
		04.2.2.8	Cooked or fried vegetables, seaweed	40 calculated in Steviol
		05.2	Candy, nougat and marzipan	700 calculated in Steviol
		05.3	Chewing gum	1100 calculated in Steviol
		06.3	Cereals for breakfast	350 calculated in Steviol
		06.5	Sweets containing cereal and starch as major component	165 calculated in Steviol
		06.8.1	Soy milk	100 calculated in Steviol
		08.3.2	Minced meat cooked by heat	100 calculated in Steviol used for brine for sausage production only
		09.3.1	Aquatic animals and their products, fermented in vinegar or wine and probably immersed in gelatin	100 calculated in Steviol used for products of sour and sweet taste only
		09.3.2	Aquatic animals and their products, fermented in brine	165 calculated in Steviol
		09.3.3	Caviar and caviar substitutes	100 calculated in Steviol
		09.4	Aquatic animals and their products treated by comprehensive food preservation processes	100 calculated in Steviol
		10.4	Sweets containing egg as major component	330 calculated in Steviol
		11.6	Sweetener	Appropriate amount Calculated in Steviol
		12.2.2	Seasoning	30 calculated in Steviol
		12.4	Mustard	130 calculated in Steviol
		12.5	Soup	50 calculated in Steviol
		12.6.1	Emulsion sauce	350 calculated in Steviol
		12.6.2	Non-emulsion sauce	350 calculated in Steviol
		12.6.3	Concentrate sauce and gravy	350 calculated in Steviol. Used for baking only.
		12.6.4	Clear sauce	350 calculated in Steviol
		12.7	Salad and sandwich spreads	115 calculated in Steviol
		12.9.2.1	Seasoning products made from soy protein digestion under fermentation	30 calculated in Steviol
		12.9.2.2	Seasoning products made from soy protein	165 calculated in Steviol

			digestion under non-fermentation	
		12.9.2.3	Seasoning products made from soy protein digestion in addition those under 12.9.2.1 and 12.9.2.2	165 calculated in Steviol
		13.3	Medical food	350 calculated in Steviol
		13.4	Foods for weight controlled person	270 calculated in Steviol
		13.5	Foods of specific nutrition purpose	660 calculated in Steviol This amount applies to products in solid form (e.g. food for weight controlled person to be consumed or partially consumed instead of regular foods) For product in liquid form, allowable up to 600 mg/kg, calculated in Steviol
		13.6	Dietary supplements	2500 calculated in Steviol used for chewing dietary supplement only
		14.1.3	Nectar vegetable and fruit juice	200 calculated in Steviol
		14.1.4	Flavored drinks not including electrolyte drinks	115 calculated in Steviol
		14.1.5	Tea, coffee, coffee substitute, herbal tea and hot drinks from cereals not including cocoa	200 calculated in Steviol used for ready-to-eat products and component for preparing ready-to-eat products
		14.2.7	Flavored alcohol drinks	200 calculated in Steviol
		15.0	Snacks	170 calculated in Steviol

End of the report.