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Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Steviol Glycosides from *Stevia rebaudiana* Bertoni as a Sweetener

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0102]

August 30, 2017

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Steviol Glycosides from *Stevia rebaudiana* Bertoni as a Sweetener

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (Regulations). Approved food additives and their permitted conditions of use are set out in the [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs and published on Health Canada’s website. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department’s Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Steviol glycosides¹ is a food additive that may be used as a sweetener in the foods and at the maximum levels set out in item S.1.2 of the [List of Permitted Sweeteners](#). Canada has permitted steviol glycosides from the stevia plant (*Stevia rebaudiana* Bertoni) to comprise one or more of ten named steviol glycosides, singly or in any combination, provided that the total steviol glycosides content is at least 95%. The ten steviol glycosides are stevioside, rebaudioside A, rebaudioside B, rebaudioside C, rebaudioside D, rebaudioside F, rebaudioside M, dulcoside A, rubusoside, and steviolbioside.

Health Canada received a food additive submission requesting that the permitted steviol glycosides content of this sweetener be expanded to include all the steviol glycosides in the *Stevia rebaudiana* Bertoni plant.

Health Canada’s evaluation of available scientific data supports this change. Consequently, the *List of Permitted Sweeteners* has been modified by removing the names of the ten steviol glycosides from the entry in column 1 of item S.1.2 of the List and by adding the name of the plant source of the steviol glycosides to this entry, as shown in the table below.

Modification to the *List of Permitted Sweeteners*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
S.1.2	Steviol glycosides from <i>Stevia rebaudiana</i> Bertoni	(1) Table-top sweeteners	(1) Good Manufacturing Practice
		(2) ... (9)	(2) ... (9)

¹ When referring to the name of the additive the term “steviol glycosides” is used in the singular.

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Rationale

Health Canada's Food Directorate completed a premarket safety assessment to expand the permitted composition of the sweetener steviol glycosides to include any of the steviol glycosides from the *Stevia rebaudiana* Bertoni plant in any combination. No change in the minimum steviol glycosides content of the sweetener (i.e., not less than 95% of the total of steviol glycosides on the dried basis) was requested.

Steviol glycosides share a common chemical structure of steviol with a sugar moiety attached at one or both of two specific positions, and from the available information they are all expected to be fermented by intestinal bacteria to steviol and one or more sugars. On the basis of this common structure and metabolism the safety assessment did not identify any toxicological food safety concerns with permitting the sweetener steviol glycosides to comprise any of the steviol glycosides from the *Stevia rebaudiana* Bertoni plant. The safety assessment also did not identify any chemical, microbiological, or nutritional food safety concerns.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as steviol glycosides from *Stevia rebaudiana* Bertoni that do not have food-grade specifications set out in Part B of the Regulations meet the most recent food-grade specifications set out in the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications*. The *Food Chemicals Codex* is a compendium of standards for purity and identity for food ingredients, including food additives, published by the United States Pharmacopeial Convention. The *Combined Compendium of Food Additive Specifications*, which contains specifications prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is published by the Food and Agriculture Organization of the United Nations (FAO) on the organization's website.

In the *List of Permitted Sweeteners*, the maximum level of use for steviol glycosides is expressed as 'steviol equivalents' as there may be numerous steviol glycoside compounds of varying molecular weights and concentrations extracted from the *Stevia rebaudiana* Bertoni plant. The molecular weights of the various steviol glycosides are different, but they all share the same general steviol chemical structure. Steviol is the reference compound and therefore the weight or concentration of steviol glycosides can be expressed on the basis of steviol content. The most common and abundant steviol glycosides in the stevia plant (*Stevia rebaudiana* Bertoni) are listed in Table 1 below. Conversion factors for each of these steviol glycosides are derived by calculating the ratio of the molecular weight of steviol to the molecular weight of the steviol glycoside of interest. Conversion is achieved for a particular steviol glycosides preparation using the factors for converting steviol glycosides to steviol equivalents shown in Table 1 below and the proportions of each steviol glycoside in the preparation of interest. For the other minor steviol glycosides compounds, which are captured in Table 1 as "all other steviol glycosides", the conversion factor is estimated to be 0.33, which is the median conversion factor for all of the major identified steviol glycosides. As the concentrations of the minor steviol glycosides in a

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steviol glycoside preparation are expected to be very low (typically no more than 5% of the total steviol glycosides content), this value is considered to be a conservative approximation.

Table 1. Factors for converting steviol glycosides to steviol equivalents

Steviol Glycoside	Molecular Weight ^a (MW; g/mol)	Conversion Factor ^b
Rebaudioside A	967.0	0.33
Rebaudioside B	804.9	0.40
Rebaudioside C	951.0	0.33
Rebaudioside D	1129.2	0.28
Rebaudioside E	967.0	0.33
Rebaudioside F	937.0	0.34
Rebaudioside M	1291.3	0.25
Rebaudioside N	1275.3	0.25
Rebaudioside O	1437.4	0.22
Rubusoside	642.7	0.50
Steviolbioside	642.7	0.50
Dulcoside A	788.9	0.40
Stevioside	804.9	0.40
All other steviol glycosides	-	0.33

^a Steviol is the reference molecule with a MW of 318.45 g/mol.

^b Conversion factor = $MW_{\text{steviol}} \div MW_{\text{steviol glycosides}}$

Implementation and Enforcement

The above modification came into force August 30, 2017, the day it was published in the [List of Permitted Sweeteners](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

Contact Information

Health Canada's Food Directorate is committed to reviewing any new scientific information on the safety in use of any food additive, including steviol glycosides from *Stevia rebaudiana* Bertoni. Anyone wishing to submit new scientific information on the use of this additive or to submit any inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**Steviol glycosides from *Stevia rebaudiana* Bertoni**" in the subject line of your e-mail.

[Bureau of Chemical Safety, Food Directorate](#)

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