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Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Rebaudioside M as a Sweetener in Various Unstandardized Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0065]

January 15, 2016

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch

Canada

Summary

Food additives are regulated in Canada under Marketing Authorizations (MAs) issued by the Minister of Health and the *Food and Drug 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.

Health Canada received a food additive submission seeking approval for the use of steviol glycosides containing the steviol glycoside "rebaudioside M" (Reb M) at a concentration of ≥50 to ≥95% as a high-intensity sweetener in the same food categories and under the same conditions of use as the currently-permitted steviol glycosides. The remainder of the composition of the steviol glycoside preparation would consist of some or all of the nine other steviol glycosides identified in the *Food Chemical Codex* (FCC) monograph.

Reb M is one of a number of steviol glycosides that are naturally present in the stevia leaf. Reb M is a minor glycoside that has recently been identified in small amounts in commercial steviol glycoside preparations where the predominant glycoside is either rebaudioside A or stevioside. The *Food Chemical Codex* (FCC) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) specifications require that steviol glycosides contain no less than 95% of the sum of nine steviol glycosides that are identified in their monograph, namely stevioside, rebaudiosides A, B, C, D and F, dulcoside A, steviolbioside, and rubusoside. Reb M is not identified in either the FCC or JECFA specifications as being one of the steviol glycosides composing the sweetener.

The results of Health Canada's evaluation of available scientific data support the safety of the steviol glycoside Reb M when used as set out in the table below. Therefore, Health Canada has modified the *List of Permitted Sweeteners* to extend the use of steviol glycoside preparations containing Reb M by adding the entry shown below to Column 1 of item S.1.2 of the list.

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 (One or any combination of Stevioside,	(1) Table-top sweeteners	(1) Good Manufacturing Practice
		(2) Breakfast cereals;	(2) 0.035% (calculated as steviol

	Rebaudioside A, Rebaudioside B, Rebaudioside C, Rebaudioside D, Rebaudioside F, Rebaudioside M, Dulcoside A, Rubusoside, and Steviolbioside, such that the total steviol glycosides content is not less than 95%)	Confectionery glazes for snack foods; Nut spreads; Peanut spreads; Sweetened seasonings or coating mixes for snack foods; Unstandardized chocolate confectionery; Unstandardized chocolate confectionery coatings; Unstandardized fruit spreads; Unstandardized purées; Unstandardized salad dressings; Unstandardized sauces; Unstandardized table syrups	equivalents)
		(3) Unstandardized beverage concentrates; Unstandardized beverages; Unstandardized beverages mixes	(3) 0.02% (calculated as steviol equivalents) in beverages as consumed
		(4) Baking mixes; Filling mixes; Fillings; Topping mixes; Toppings; Unstandardized bakery products; Unstandardized dessert mixes; Unstandardized desserts; Yogurt	(4) 0.035% (calculated as steviol equivalents) in products as consumed
		(5) Breath freshener products; Chewing gum	(5) 0.35% (calculated as steviol equivalents)
		(6) Unstandardized condiments	(6) 0.013% (calculated as steviol equivalents)
		(7) Unstandardized confectionery (except unstandardized chocolate confectionery); Unstandardized confectionery coatings (except unstandardized	(7) 0.07% (calculated as steviol equivalents)

		chocolate confectionery coatings)	
		(8) Meal replacement bars	(8) 0.02% (calculated as steviol equivalents)

Rationale

Health Canada's Food Directorate completed a pre-market safety assessment of the requested uses of steviol glycoside preparations containing Reb M at a concentration of ≥50 to ≥95%. The assessment considered microbiological, toxicological, nutritional, and chemical aspects of this additive, and found that the requested uses are acceptable from a food safety perspective. Therefore, the Department has enabled the requested uses of steviol glycoside preparations containing Reb M by modifying the *List of Permitted Sweeteners* as described in the above table.

Other Relevant Information

The 47th Session of the Codex Committee on Food Additives (CCFA) submitted a request to JECFA via the "Priority List of Substances Proposed for Evaluation by JECFA" for a safety assessment and revision of specifications for steviol glycosides to (1) include rebaudiosides M and E, and (2) delete the requirement that the primary steviol glycosides in stevia preparations be stevioside and/or Reb A.[1] JECFA has issued a call for data so that the request can be considered at the Expert Committee's 82nd meeting in June 2016.

Two "self-affirmed" GRAS notifications have been filed with the U.S. Food and Drug Administration (US FDA) for steviol glycosides containing Reb M as a principle component. In both notifications, the intended use is as a general purpose sweetener in foods (excluding meat and poultry products and infant formula) at levels consistent with GMP and as a tabletop sweetener. The FDA had no questions at the time regarding the petitioners' conclusions that under the intended conditions of use the sweetener was GRAS.

Food Standards Australia New Zealand (FSANZ) has evaluated an application seeking approval to use steviol glycoside preparations containing Reb M at a concentration of ≥50% to ≥95% as an intense sweetener. FSANZ raised no public health and safety concerns with the use of Reb M as a food additive in accordance with the current provisions for steviol glycosides. A new specification for Reb M is anticipated in mid-January 2016 in Schedule 3 of the revised Food Standards Code.[2]

1 See the Report of the 47th Session of the Codex Committee on Food Additives (REP 15/FA) and the Addendum 1 document for Agenda Item 7a of that meeting (CX/FA 15/47/16 Add.1).
2 Call for Submissions – Application A1108, Rebaudioside M as a Steviol Glycoside Intense Sweetener, 29 June 2015

Steviol glycosides have been permitted to be added to foods in the European Union (EU) since 2011.[3] Although the EU's specifications for steviol glycosides do not currently refer to Reb M as one of the steviol glycosides in this sweetener[4], the European Food Safety Authority published, on December 8, 2015, its scientific opinion that extending the current specifications for steviol glycosides to include Reb M would not be a safety concern.[5]

Implementation and Enforcement

The above modification came into force **January 15, 2016**, 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 containing Reb M. 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 Reb M**" in the subject line of your e-mail.

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3 Commission Regulation (EU) No 1131/2011 of 11 November, 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regards to steviol glycosides. Off J Eur Union 54 (L295): 205-211

4 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (text with EEA relevance). Pdf version of *Official Journal of the European Union*, L 83/1, 22.3.2012

5 Scientific opinion on the safety of the proposed amendment of the specifications for steviol glycosides (E 960) as a food additive, EFSA Journal 2015; 13(12): 4316.