Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Steviol Glycosides as a Table-Top Sweetener and as a Sweetener in Certain Food Categories

Notice of Modification – Lists of Permitted Food Additives
Document Reference Number: [NOM/ADM-0002]

November 30, 2012
Summary

Further to Health Canada’s technical consultation published on July 31, 2012, entitled *Information and Consultation Document on Health Canada’s Proposal to Allow the Use of the Food Additive Steviol Glycosides as a Table-Top Sweetener and as a Sweetener in Certain Food Categories*, Health Canada is modifying the Lists of Permitted Food Additives as indicated in the table below.

Food additives are regulated in Canada under the *Food and Drug Regulations* and *Marketing Authorizations* (MAs) issued by the Minister of Health. 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. 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 three separate food additive submissions that together seek approval for the use of steviol glycosides as a table-top sweetener and a sweetener in a variety of unstandardized foods. The results of Health Canada’s evaluation of available data support the safety and efficacy of steviol glycosides when used as described. Therefore, Health Canada has enabled the following use(s) of the food additive steviol glycosides by modifying the *List of Permitted Sweeteners* by adding the following entries to the list:

**Modification to the List of Permitted Sweeteners**

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Column 1 Additive</th>
<th>Column 2 Permitted in or upon</th>
<th>Column 3 Maximum Level of Use and Other Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.1.2</td>
<td>Steviol glycosides</td>
<td>(1) Table-top sweeteners</td>
<td>(1) Good Manufacturing Practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2) Breakfast cereals; Confectionery glazes for snack foods; Nut spreads; Peanut spreads;</td>
<td>(2) 0.035% (calculated as steviol equivalents)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sweetened seasonings or coating mixes for snack foods; Unstandardized chocolate confectionery</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unstandardized chocolate confectionery coatings;</td>
<td></td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Unstandardized fruit spreads; Unstandardized purées; Unstandardized salad dressings; Unstandardized sauces; Unstandardized table syrups</th>
<th>(3) Unstandardized beverage concentrates; Unstandardized beverages; Unstandardized beverages mixes</th>
<th>(3) 0.02% (calculated as steviol equivalents) in beverages as consumed</th>
</tr>
</thead>
<tbody>
<tr>
<td>(4) Baking mixes; Filling mixes; Fillings; Topping mixes; Toppings; Unstandardized bakery products; Unstandardized dessert mixes; Unstandardized desserts; Yogurt</td>
<td>(4) 0.035% (calculated as steviol equivalents) in products as consumed</td>
<td></td>
</tr>
<tr>
<td>(5) Breath freshener products; Chewing gum</td>
<td>(5) 0.35% (calculated as steviol equivalents)</td>
<td></td>
</tr>
<tr>
<td>(6) Unstandardized condiments</td>
<td>(6) 0.013% (calculated as steviol equivalents)</td>
<td></td>
</tr>
<tr>
<td>(7) Unstandardized confectionery (except unstandardized chocolate confectionery); Unstandardized confectionery coatings (except unstandardized chocolate confectionery coatings)</td>
<td>(7) 0.07% (calculated as steviol equivalents)</td>
<td></td>
</tr>
</tbody>
</table>
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Notification

Health Canada’s Information and Consultation Document on Health Canada’s Proposal to Allow the Use of the Food Additive Steviol Glycosides as a Table-Top Sweetener and as a Sweetener in Certain Food Categories was published for a 75 day comment period beginning on July 31, 2012 and ending on October 14, 2012. During the course of this consultation, Health Canada received a number of comments which are summarized below.

Summary of Comments Received

In total, 27 comments were received citing support of Health Canada’s proposal to enable the use of steviol glycosides as a table-top sweetener and as a sweetener in certain food categories. Comments were received primarily from food industry associations. One patient group also indicated support.

In several instances, respondents requested that the common names "purified stevia extract" and "stevia leaf extracts" be permitted for use on labels. Some respondents also requested general clarification of the permitted use(s) of steviol glycosides and asked technical questions, all of which have either been directly responded to by the Food Directorate’s Bureau of Chemical Safety, or referred to the most appropriate Government of Canada resource. In the case of the common names that would be acceptable for use on food labels, the Canadian Food Inspection Agency can be consulted to obtain information on labelling requirements for food additives.

It should be noted that some comments were received requesting the use of steviol glycosides in additional food categories. It has been clarified in these instances that any requests for additional food additive use(s) of steviol glycosides outside of what has been proposed through Health Canada’s recent online consultation can be addressed through the provision of a food additive submission pursuant to section B.16.002, Division 16 of the Food and Drug Regulations. Please refer to the following detailed information which provides guidance on the completion of a food additive submission.

After due consideration of the overall weight of scientific evidence supporting the safety of Health Canada’s proposal, as well as the comments received through Health Canada’s corresponding consultation, the Department has modified the List of Permitted Sweeteners to enable the use(s) of steviol glycosides as outlined in the table above.

Implementation and Enforcement

The above modification came into force the day on which it is published in the List of Permitted Sweeteners.

The Canadian Food Inspection Agency (CFIA) is responsible for compliance and enforcement of the Food and Drugs Act and its associated regulations with respect to foods.
Contact Information

For additional information or to submit information related to this modification to the List of Permitted Sweeteners, please contact the Food Directorate’s Bureau of Chemical Safety.

Bureau of Chemical Safety
251 Sir Frederick Banting Driveway
Tunney’s Pasture, PL: 2202C
Ottawa, Ontario K1A 0L2

E-mail: bcs-bipc@hc-sc.gc.ca

If communicating by e-mail, please use the words “steviol glycosides” in the subject box of your e-mail.