Current trends show that Canadians are looking for foods that are nutritious, lower in calories, and taste great. This reflects growing consumer concerns about issues such as weight control and improving overall health. Consumer research indicates that sugar content is the third most influential consideration when making food choices. Low and zero calorie sweeteners, or nonnutritive sweeteners (NNS), meet this consumer need by providing an alternative to sugars and other caloric sweeteners, particularly for those who are looking for a sweet taste without significant calories.

Extensive evidence supports the safety of NNS and their potential role in weight management. As a result, food and beverage manufacturers are working to expand product offerings that are reduced or low in calories, using existing or new NNS. Recently, Health Canada approved the use of purified steviol glycosides, sweeteners derived from the Stevia plant, in certain foods and beverages. This resource will provide an overview of the rigorous Health Canada review process and subsequent approval of the steviol glycosides, and will address frequently asked questions around the safety of NNS.

A number of sugar substitutes are available in Canada with uses ranging from table-top sweeteners to low calorie foods and beverages. Sweeteners are often used alone or in combination with other sweeteners and flavours, depending on the desired taste. Some are considered high-intensity sweeteners because they are much sweeter than sugar (sucrose), and can replace the sweetness of sugar or other energy-containing sweeteners.

Before a new sweetener is approved for use in Canada, companies that produce this sweetener must provide a robust submission supported by scientific evidence that includes information related to the safety, allergenicity, estimated consumption patterns, and proposed uses of the sweetener. These submissions are subject to a thorough safety evaluation by Health Canada. Once deemed safe, Health Canada initiates a public notification period to provide Canadians with the opportunity to raise science-based safety concerns for their review. Proposed concerns or amendments are evaluated and changes are made when necessary. Once the sweetener is approved it is then added to the List of Permitted Sweeteners which specifies amounts and types of products that it can be used in.

### APPROVAL OF LOW-CALORIE SWEETENERS IN CANADA

Most recently, purified steviol glycosides underwent review by Health Canada and in November 2012, they were deemed safe for use in certain foods and beverages at particular levels.

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**Table 1: Permitted Sweeteners in Canada**

<table>
<thead>
<tr>
<th>High Intensity Sweeteners</th>
<th>Sweetness (Compared with Sucrose)</th>
<th>Sugar Alcohols</th>
<th>Sweetness (Compared with Sucrose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neotame</td>
<td>7000-13000x</td>
<td>Xylitol</td>
<td>100%</td>
</tr>
<tr>
<td>Thaumatin</td>
<td>2000-3000x</td>
<td>Maltitol</td>
<td>90%</td>
</tr>
<tr>
<td>Sucralose</td>
<td>600x</td>
<td>Hydrogenated Starch Hydrolysate</td>
<td>40-90%</td>
</tr>
<tr>
<td>Saccharin**</td>
<td>300-400x</td>
<td>Erythritol</td>
<td>70%</td>
</tr>
<tr>
<td>Steviol Glycosides*</td>
<td>200-300x</td>
<td>Isomalt</td>
<td>45-65%</td>
</tr>
<tr>
<td>Acesulfame potassium</td>
<td>200x</td>
<td>Sorbitol</td>
<td>60%</td>
</tr>
<tr>
<td>Aspartame</td>
<td>180x</td>
<td>Mannitol</td>
<td>50%</td>
</tr>
<tr>
<td>Cyclamate</td>
<td>30x</td>
<td>Lactitol</td>
<td>40%</td>
</tr>
</tbody>
</table>

Sweetness level as reported by the Calorie Control Council.

* Sweetness level of steviol glycosides as reported by Health Canada.

** Sweetness level as reported by the European Food Information Council.

Note: Saccharin sweeteners may only be sold in pharmacies. Cyclamate can only be used as a table top sweetener. Both are not part of the List of Permitted Sweeteners but are permitted for use under special regulations.
BACKGROUND

Stevia Rebaudiana, commonly known as stevia, is a plant native to Paraguay and is a member of the Asteraceae family. Stevia is widely cultivated in South America where it has been used as a natural sweetener for more than a century. Today, much of the world’s commercial supply originates in Asia.10

The leaves of the stevia plant contain high potency sweeteners called steviol glycosides.10 Although there is some variation in the production of steviol glycosides among different manufacturers, in general, the process involves steeping the dry leaves in hot water, filtering out any solid material and crystalizing the remaining solution.10 Further purification is needed to yield a 95% pure steviol glycoside extract that contains a mixture of up to nine different glycosides.6

Steviol glycosides have a sweet taste and may be up to 200-300 times as sweet as sugar, but the extract may also have a slightly bitter after taste, depending on the composition. The nine glycosides vary slightly in taste and due to the more favourable taste profile of rebaudioside A (reb A), commercial plant breeding has focused on increasing the amount of reb A in the plant.10 While the molecular weights of the nine glycosides are different, they share the same general steviol chemical structure. Therefore, the amount of the total steviol glycosides, particularly if they are used in combination, can be expressed based on the steviol content termed as “steviol equivalents.”6

HEALTH CANADA APPROVAL

Health Canada received submissions requesting the use of steviol glycosides in a variety of foods and as table-top sweeteners. On November 30, 2012, following their scientific assessment, and consultation period, Health Canada added steviol glycosides to the List of Permitted Sweeteners to enable its use as a table-top sweetener and as a sweetener in certain food and beverage categories. A summary table of this safety assessment is found below including their evaluation of toxicity, allergenicity, and nutritional assessment.

Table 2: Summary of Safety Data on Steviol Glycosides 6

<table>
<thead>
<tr>
<th>ASSESSMENT</th>
<th>FINDINGS</th>
</tr>
</thead>
</table>
| Toxicological Assessment | • After 96 hours following oral exposure, about 90-100% of ingested steviol glycosides were excreted and no accumulation of steviol glycosides derivatives occurred in animal studies.  
• Acute oral exposure of very large doses (up to 15 g/kg bw) in mice, rats and hamsters indicated low oral toxicity.  
• Short-term oral exposure of large doses (up to 1.2 g/kg bw/day) in rats and dogs showed no systemic toxicity.  
• Long-term exposure of large doses (up to 0.4 g/kg bw/day) in rats showed no evidence of systemic toxicity or carcinogenicity.  
• Through a series of studies, purified steviol glycosides were shown to have no adverse effect on genetic material.  
• Reproductive and developmental studies in rats, hamsters and rabbits using large doses (up to 1 g/kg bw/day) showed no reproductive toxicity or developmental anomalies (birth defects).  
• Clinical studies with healthy human volunteers and individuals with type II diabetes mellitus showed no adverse effects on blood pressure or blood glucose after ingesting daily doses of steviol glycosides over 2 years (7.6 mg/kg bw/day). No adverse effects were shown on standard parameters of clinical chemistry, hematology or urinalysis. |
| Allergenicity Assessment | • The European Food Safety Authority (EFSA) concluded in its opinion on the safety of steviol glycosides that “it is unlikely that the steviol glycosides under evaluation should cause, by themselves, allergic reactions when consumed in foods.”  
• No published reports of allergic reactions to stevia products such as stevia leaves or stevioside in either healthy or allergic populations. |
| Nutritional Assessment | • No concerns                                                                                                                                 |

The submissions to Health Canada for steviol glycoside approval were deemed sufficient for Health Canada to establish an Acceptable Daily Intake (ADI) for purified steviol glycosides of 4 mg steviol equivalents/kg of body weight (bw).6 The ADI for a 70 kg person is 280 mg steviol equivalents per day. To put this into context, in the case of a beverage, if the maximum level of steviol equivalents were utilized (0.02%), then it would contain approximately 70 mg steviol equivalents per 355 mL serving, which is well below the ADI.

DIETARY EXPOSURE FROM FOOD CATEGORIES

The estimated dietary exposure of steviol glycosides from foods and beverages used the 24-hour food intake recall data from the Canadian Community Health Survey (CCHS) and assumed the widespread use of steviol glycoside at the proposed maximum levels. The estimated exposure was then compared with the acceptable daily intake (ADI) of 4 mg steviol equivalents/kg bw. Median exposure for all age and sex groups in this model were below the ADI and thus it was determined that the proposed levels for use in foods and beverages were deemed appropriate.6
Noncaloric, low calorie or high-intensity sweeteners are of great interest as they are much sweeter than table sugar (sucrose) and thus provide sweetness while adding only few or no calories per serving. For example, 1 g of aspartame can replace 200 g of sucrose, providing four kilocalories of energy instead of 800 kilocalories. Amongst the most commonly used low calorie sweeteners in Canada are acesulfame potassium (Ace K), aspartame, and sucralose. Often individuals express concerns about the use of these sweeteners and potential effects they may have on health. These sweeteners have been extensively reviewed by Health Canada, and based on available studies, have been approved for use. Below, a number of questions about the safety of NNS are addressed.

1. Do low calorie sweeteners cause cancer?
This has been a controversial question for a number of the sweeteners on the market. Low calorie sweeteners are extensively evaluated prior to approval, and must be shown to not be carcinogenic when added to foods or beverages. Although there have been some reports that claim that low calorie sweeteners can cause cancer, regulatory authorities around the world carefully review these studies, and continue to conclude that the sweeteners are safe. For example, there have been several reports from one laboratory in Italy, stating that aspartame causes cancer in rats and mice. This is in contrast to the many studies on aspartame showing it does not cause cancer. The consensus of many experts (EFSA, FDA, Health Canada) is that the Italian studies are critically flawed and the results are not valid.

2. Do low calorie sweeteners make you eat more?
Many studies have been conducted to answer this question for adults and children. Two recent reviews of these studies have concluded that the answer is ‘no’. A systematic meta-analysis was conducted on 16 studies assessing effect of aspartame on weight loss. Only studies that measured energy intake for at least 24 h and/or measured weight changes were included. Although there were variations in design, study population, duration and type of control, the meta-analysis concluded that consumption of foods and drinks sweetened with aspartame instead of sucrose resulted in a significant reduction in both energy intake and body weight.

There is also no support for the claim that low calorie sweeteners make you crave sweets. In fact, studies of free-living users of low calories sweeteners have demonstrated that these sweeteners can be useful in limiting caloric intake, when they are used as part of a healthy diet.

3. Do any of the low calorie sweeteners accumulate in the body?
No. All the low calorie sweeteners are either (1) completely broken down during digestion; (2) not absorbed and excreted in the feces; or (3) absorbed and completely eliminated in the urine. Aspartame is completely digested in the small intestine into two amino acids (aspartic acid and phenylalanine) and a small amount of methanol. Aspartame is never absorbed intact and can never be found in human tissue. The amount of amino acids and methanol from aspartame is much less than the amounts found in common foods and fruit juices. Only individuals with the rare genetic condition, phenylketonuria, must limit consumption of phenylalanine, so warnings of phenylalanine content are required on products containing aspartame.

Ace K, the potassium salt of acesulfame, is rarely used alone but is commonly blended with aspartame or other sweeteners. Ace K is rapidly absorbed and excreted unchanged in the urine within 24 hours in rats, dogs and humans.

Steviol glycosides are responsible for sweetness of stevia-based sweeteners. Steviol glycosides are not absorbed in the small intestine, but reach the colon where they are converted to steviol by gut microflora. Steviol is absorbed in the colon, metabolized in the liver, and excreted in human urine.

Sucralose is not well absorbed and most is eliminated unchanged in feces.

4. Should you avoid low calorie sweeteners during pregnancy?
All of the sweeteners that are approved as food additives for use in processed foods and beverages have been tested to ensure they are safe to consume during pregnancy. Thus, if a pregnant woman chooses to limit her sugar intake, she can confidently use foods and beverages with low caloric sweeteners.

5. Can low calorie sweeteners cause behavior disorders in children?
The effect of aspartame on behavior has been extensively studied in children, under a variety of conditions. This includes studies on normal children, hyperactive children, aggressive school boys, and children thought to be sugar-sensitive. In all cases, when the treatments were blind to the observer, aspartame consumption had no effect on behavior of children. No studies of the effect of other low calorie sweeteners on behavior in children were identified.

6. Is there any association between consuming aspartame and development of multiple sclerosis?
According to various Multiple Sclerosis Foundations there is no evidence supporting the claim that aspartame could cause certain diseases (i.e. multiple sclerosis, lupus, etc.). The Multiple Sclerosis Society of Canada refutes the claims made against aspartame and notes that there has been no published peer-reviewed research on aspartame and multiple sclerosis, which support such claims.
Low calorie sweeteners are found in a variety of food and beverage products. You can help to educate your clients about the types of low and zero calorie sweeteners available, and how to read ingredient lists to understand the quantity of sweetener in each serving.

Look for names like:
- ASPARTAME
- SUCRALOSE
- ACE K
- SUCRALOSE + ACE K
- REB A
- REB A + ERYTHRITOL
- STEVIA

The following is an example of how sweeteners will appear on the label:

**Diet Pepsi**

**INGREDIENTS:** CARBONATED WATER, CARAMEL COLOUR, SODIUM BENZOATE, CAFFEINE, NATURAL FLAVOUR, SUCRALOSE POTASSIUM (32mg/355mL), CITRIC ACID, DIMETHYLPOLYSILOXANE.

The following is an example of how sweeteners will appear on the label:

**IN THE MARKETPLACE**

PepsiCo Canada uses a variety of low calorie sweeteners in their products. These products either contain a single sweetener or a combination of sweeteners to achieve the desired taste. Below are a selection of products made with low calorie sweeteners offered by PepsiCo Canada.

**REFERENCES**

17. FDA. Available at: http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm208580.htm