Health Canada’s Proposal to Enable the Use of a New Food Additive, Advantame, as a Sweetener in Certain Unstandardized Foods Including Certain Beverages

Notice of Proposal – Lists of Permitted Food Additives

Reference Number: [NOP/AVP-0022]

October 27, 2016
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 advantame as a sweetener in certain unstandardized foods, including unstandardized beverages. Advantame is structurally similar to aspartame, a sweetener that is already permitted for use, but it is approximately 70 to 120 times sweeter than aspartame, depending on the sweetness intensity (i.e., concentration of aspartame) that is used to compare the two.

The results of Health Canada’s evaluation of available scientific data support the safety and efficacy of advantame when used as requested by the petitioner. Therefore, Health Canada intends to enable the use of this new sweetener by adding the following entries to the List of Permitted Sweeteners.

Proposed 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>A.02</td>
<td>Advantame</td>
<td>(1) Table-top sweeteners</td>
<td>(1) Good Manufacturing Practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(2) Baking mixes; Unstandardized bakery products</td>
<td>(2) 18 p.p.m. in products as consumed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(3) Breakfast cereals; Nut spreads; Peanut spreads; Unstandardized fruit spreads; Unstandardized purées; Unstandardized table syrups</td>
<td>(3) 10 p.p.m.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(4) Unstandardized beverages except unstandardized coffee beverages and unstandardized tea beverages; Unstandardized beverage concentrates; Unstandardized beverage mixes</td>
<td>(4) 10 p.p.m. in products as consumed</td>
</tr>
</tbody>
</table>
except unstandardized coffee beverage mixes and unstandardized tea beverage mixes; Unstandardized desserts; Unstandardized dessert mixes

(5) Unstandardized coffee beverages; Unstandardized coffee beverage mixes; Unstandardized tea beverages; Unstandardized tea beverage mixes

(5) 3 p.p.m. in beverages as consumed

(6) Breath freshener products; Chewing gum

(6) 400 p.p.m.

(7) Confectionery glazes for snack foods; Sweetened seasonings or coating mixes for snack foods; Unstandardized confectionery; Unstandardized confectionery coatings

(7) 20 p.p.m.

(8) Fillings; Filling mixes; Toppings; Topping mixes

(8) 20 p.p.m in products as consumed

(9) Marinades

(9) 3 p.p.m.

(10) Unstandardized salad dressings

(10) 5 p.p.m.

(11) Unstandardized condiments; Unstandardized sauces

(11) 4 p.p.m.

(12) Broths; Soups; Soup mixes

(12) 2 p.p.m. in products as consumed

(13) Dietetic confectionery; Dietetic confectionery coatings

(13) 60 p.p.m.

(14) Yogurt

(14) 6 p.p.m.

Rationale

Health Canada conducted a premarket assessment of advantame for use as a food sweetener. The assessment considered chemical, toxicological, and nutritional aspects of the submission, as well as information about advantame’s technical function as a sweetener.

Like aspartame, advantame releases the amino acids phenylalanine and aspartic acid during digestion. Both of these amino acids are normal dietary constituents but because of the small
amount of advantame required to sweeten foods, the contribution of these amino acids to the diet would be nutritionally insignificant.

The small amount of phenylalanine released from advantame when used as a sweetener is also insignificant for persons with phenylketonuria (PKU) who must restrict their intake of phenylalanine because of an inability to metabolise it.¹

Toxicological testing with advantame found it was not mutagenic, genotoxic, or carcinogenic, and did not elicit reproductive or developmental toxicity. In clinical studies with human volunteers, advantame was well-tolerated by healthy individuals and those with Type 2 diabetes. Conservative estimates of dietary exposure to advantame from its use in the requested foods are considered acceptable from a toxicological perspective.

The results of studies of the long-term stability of advantame in food and beverage matrices under a wide range of temperature, pH, moisture, and light conditions were submitted to demonstrate that advantame is stable under its intended conditions of use. Some advantame can be hydrolyzed to advantame acid and methanol under acidic conditions, such as those found in some beverage products, and over a storage period that is greater than the typical shelf life of most beverages. The resulting small amount of these and other possible impurities raised no toxicological concerns.

The available safety information supports the use of advantame under the conditions set out in the table above. The Department is therefore proposing to enable the use of advantame as described in the table.

**Other Relevant Information**

Advantame is permitted for use as a sweetener in the United States, Europe, and Australia and New Zealand, and food additive provisions for advantame (INS 969) are being considered for inclusion in the Codex General Standard for Food Additives (GSFA). The GSFA is an internationally-developed standard for the use of food additives.

The Canadian *Food and Drug Regulations* require that food additives such as advantame, which do not have specifications set out in the Regulations, meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC). The FCC is a compendium of standards for purity and identity for food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

¹This conclusion is consistent with that reached by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which is an international body of experts that assesses the safety of food additives (Safety evaluation of certain food additives and contaminants. *WHO Food Additives Series*: 68. World Health Organization 2013).
Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the *List of Permitted Sweeteners*. This will be announced via a Notice of Modification which will be published on Health Canada’s Website.

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

For additional information or to submit comments related to this proposal, please contact:

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If communicating by e-mail, please use the word “Advantame” in the subject line of your e-mail. Health Canada is able to consider information received by January 09, 2017, 75 days from the date of this posting.