



Health  
Canada

Santé  
Canada

Your health and  
safety... our priority.

Votre santé et votre  
sécurité... notre priorité.

# Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0026]

April 24, 2014

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 Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods

### Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (FDR). 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 a food additive submission seeking approval for the use of saccharin as a sweetener in various unstandardized foods.

On October 7, 2013, Health Canada published a [Consultation Document on Health Canada's Proposal to Enable the Use of Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods](#) seeking comments on the proposal. No new scientific information was submitted to the Department as a result of this publication. Since the conclusions of the evaluation remain as described in the publication, Health Canada has modified the [List of Permitted Sweeteners](#) as described in that document with one minor change, namely to the description of the food category "Unstandardized non-alcoholic beverages". For the purpose of clarification, Health Canada has modified this food category as it appears in column 2 of the table to read "Unstandardized carbonated non-alcoholic beverages". This wording more accurately describes the food category requested in the submission and which was considered in the safety evaluation.

The results of Health Canada's evaluation of available scientific data support the safety of saccharin, calcium saccharin, potassium saccharin and sodium saccharin when used as described 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
C.1	Calcium saccharin	Same foods as listed for Saccharin	Same levels and conditions as prescribed for saccharin
P.1	Potassium saccharin	Same foods as listed for Saccharin	Same levels and conditions as prescribed for saccharin
S.01	Saccharin	(1) Breath freshener products	(1) 0.15% calculated as saccharin. If any combination of saccharin, calcium saccharin,

**Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods**

			potassium saccharin or sodium saccharin is used, the total amount not to exceed 0.15%, calculated as saccharin.
		(2) Unstandardized canned fruit	(2) 0.01% calculated as saccharin. If any combination of saccharin, calcium saccharin, potassium saccharin or sodium saccharin is used, the total amount not to exceed 0.01%, calculated as saccharin.
		(3) Chewing gum	(3) 0.25% calculated as saccharin. If any combination of saccharin, calcium saccharin, potassium saccharin or sodium saccharin is used, the total amount not to exceed 0.25%, calculated as saccharin.
		(4) Unstandardized frozen desserts	(4) 0.0025% calculated as saccharin. If any combination of saccharin, calcium saccharin, potassium saccharin or sodium saccharin is used, the total amount not to exceed 0.0025%, calculated as saccharin.
		(5) Toppings; Topping Mixes	(5) 0.09% calculated as saccharin. If any combination of saccharin, calcium saccharin, potassium saccharin or sodium saccharin is used, the total amount not to exceed 0.09%, calculated

**Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods**

			as saccharin.
		(6) Unstandardized alcoholic liqueurs	(6) 0.12% calculated as saccharin. If any combination of saccharin, calcium saccharin, potassium saccharin or sodium saccharin is used, the total amount not to exceed 0.12%, calculated as saccharin.
		(7) Unstandardized carbonated non- alcoholic beverages	(7) 0.03% calculated as saccharin. If any combination of saccharin, calcium saccharin, potassium saccharin or sodium saccharin is used, the total amount not to exceed 0.03%, calculated as saccharin.
		(8) Unstandardized fruit spreads	(8) 0.02% calculated as saccharin. If any combination of saccharin, calcium saccharin, potassium saccharin or sodium saccharin is used, the total amount not to exceed 0.02%, calculated as saccharin.
S.01.1	Sodium Saccharin	Same foods as listed for saccharin	Same levels and conditions as prescribed for saccharin

## Rationale

Health Canada's Food Directorate has completed a pre-market safety assessment of saccharin, calcium saccharin, potassium saccharin and sodium saccharin when used as described above. The assessment focused on toxicological aspects of the proposal.

Based on the results of the safety assessment and the fact that no new scientific safety information has become available that would alter the conclusions of the safety assessment, Health Canada considers that the data demonstrate the safety of saccharin, calcium saccharin,

## Notice of Modification to the *List of Permitted Sweeteners to Enable the Use of Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods*

potassium saccharin and sodium saccharin as sweeteners under the conditions of use set out above. The Department has therefore enabled the use of saccharin as described in the above table.

### Other Relevant Information

Saccharin, calcium saccharin and sodium saccharin used in foods sold in Canada must 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 of food ingredients, including food additives, which is published by the United States Pharmacopeial Convention. Since the FCC does not currently have a monograph with specifications for potassium saccharin (at the time of the publication of this document), Health Canada considers the food-grade specifications for potassium saccharin established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to be acceptable.

As described in the *Consultation Document on Health Canada's Proposal to Enable the Use of Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods*, Health Canada intends to enable the use of saccharin, calcium saccharin, potassium saccharin, and sodium saccharin as food additives in table-top sweeteners. As food additives, they would be subject to the general food additive requirements set out in Part B of the FDR. In the meantime, saccharin and its salts as listed above continue to be permitted for sale as saccharin sweeteners under specific labelling and point-of-sale conditions prescribed in Part E of the *Food and Drug Regulations* (FDR).

### Notification – Summary of Comments

In response to the [\*Consultation Document on Health Canada's Proposal to Enable the Use of Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods\*](#), published on October 7, 2013, Health Canada received four comments.

Three comments were received from domestic and foreign industry associations. A fourth was received from a national government. All three association responses indicated support for the proposal.

One of these associations and a national government requested that modifications to the listing be made to allow for broader use of these food additives. In response, Health Canada has indicated that the permitted foods and the maximum levels of use are based on the results of the safety evaluation of the requested maximum levels of use and the requested foods set out in the food additive submission, and that the Department can consider a new food additive submission requesting an extension of use for these sweeteners to include a new food or a different maximum level of use.

## Implementation and Enforcement

The above modification came into force April 24, 2014, 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 new scientific information on the safety in use of any permitted food additive, including saccharin, calcium saccharin, potassium saccharin and sodium saccharin. Anyone wishing to submit new scientific information on the use of these food additives 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 word "**saccharin**" in the subject line of your e-mail.

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

251 Sir Frederick Banting Driveway  
Tunney's Pasture, PL: 2202C  
Ottawa, Ontario K1A 0L2  
E-mail: [bc-s-bipc@hc-sc.gc.ca](mailto:bc-s-bipc@hc-sc.gc.ca)