



Français	Contact us	Help	Search	Canada Site
Home	About us	History	FAQ	Site Map

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[Notice](#)

Quick Search

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[News and announcements](#)[Mandate](#)[Consultation](#)[Recent Canada Gazette publications](#)[Part I: Notices and proposed regulations](#)[Part II: Official regulations](#)[Part III: Acts of Parliament](#)[Learn more about the Canada Gazette](#)[Publishing information](#)[Publishing requirements](#)[Deadline schedule](#)[Insertion rates](#)[Request for insertion forms](#)[Subscription information](#)[Useful links](#)[Archives \(1998-2005\)](#)

Regulations Amending the Food and Drug Regulations (1433 — Neotame)

*Statutory authority**Food and Drugs Act**Sponsoring department*

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

High intensity sweeteners used in the manufacture of foods are considered, under the *Food and Drug Regulations*, to be food additives. The high intensity sweeteners permitted under the *Food and Drug Regulations* are aspartame, sucralose and acesulfame-potassium. The use of a new high intensity sweetener can only be accommodated by amendment of the Regulations following a thorough evaluation of its safety.

Health Canada has received a submission to amend the *Food and Drug Regulations* to permit the use of neotame, a substance that is 7 000 to 13 000 times sweeter than sugar. Neotame would be used as a high intensity sweetener in carbonated soft drinks, beverage concentrates, beverage mixes (powdered soft drinks, pre-sweetened cocoa, or coffee mixes), unstandardized dairy beverages, unstandardized fruit juices, breakfast cereals, dessert mixes, toppings, topping mixes, fillings, filling mixes, unstandardized desserts, yogurt, confectionery glazes for snack foods, sweetened seasonings or coating mixes for snack foods, confections, including candies and their coatings, chewing gum,

breath freshener products, unstandardized fruit spreads, purées, sauces, unstandardized table syrups, unstandardized salad dressings, peanut and other nut spreads, condiments, unstandardized baked goods, baking mixes, and as a table-top sweetener at maximum levels of use specified in the proposed amendments.

Evaluation of available data supports the safety and effectiveness of these uses of neotame. Similar applications of this food additive are already permitted in the United States, Australia, New Zealand and Europe.

Under the current Regulations, all foods (including those that are table-top sweeteners) that contain aspartame, acesulfame-potassium or sucralose must carry a statement on the principal display panel to the effect that the food contains or is sweetened with the sweetener. For foods carrying a nutrition facts table, the sweetener content expressed in milligrams per serving of stated size must be declared on their labels. In the case where the label of the food does not carry a nutrition facts table, information on the energy value expressed in Calories or kilojoules, the protein, fat, and carbohydrate content, expressed in grams per serving of stated size, and the sweetener content expressed in milligrams per serving of stated size, must be provided on any part of the label, grouped with the list of ingredients. The same requirements are proposed for foods containing neotame.

The proposed regulatory amendments would also consolidate the conditions for the use of the claim "low Calorie" in English on labels of sweeteners within the table of nutrient content claims following section B.01.513 of the Regulations. Health Canada is proposing to revoke subsections B.01.015(2), B.01.017(2) and B.01.020(2) and to amend item 2 of the table following section B.01.513 to include conditions for the use of the "low Calorie" claim specifically for sweeteners.

The revocation of the subsections mentioned above would delete the claim "faible teneur en calories" in French that is currently permitted for use on the label of these products. However, the proposed amendments would provide industry with more options under item 2 of the table following section B.01.513 to make other "low in energy" claims on their products. These options would include the use of the claim "hypocalorique."

Therefore, it is the intention of Health Canada to recommend that the *Food and Drug Regulations* be amended to permit the use of neotame in the above-named foods at the specified maximum levels of use and to require that the label of a food containing neotame carries the information indicated above.

Alternatives

Under the *Food and Drug Regulations*, additional provisions for the use of new or already permitted food additives in foods can only be accommodated by regulatory amendment. Maintaining the status quo was rejected, as this would preclude the use of a food additive which has been demonstrated to be both safe and effective.

Benefits and costs

The proposed amendments would provide the consumer and the industry with an alternative to currently available sweeteners.

There is no anticipated increase in cost to Government from the administration of the proposed amendments to the Regulations. Furthermore, compliance costs incurred by manufacturers are not considered to be a factor, as the use of neotame would be optional.

Consultation

Because of the proprietary nature of submissions which deal with food additives, consultation on the proposed amendments is not carried out prior to prepublication in the *Canada Gazette*, Part I.

Compliance and enforcement

If these proposed amendments are adopted, compliance will be monitored by ongoing domestic and import inspection programs of the Canadian Food Inspection Agency.

Contact

Ronald Burke, Director, Bureau of Food Regulatory, International and Interagency Affairs, Health Canada, 200 Tunney's Pasture Driveway, Address Locator 0702C1, Ottawa, Ontario K1A 0L2, 613-957-1828 (telephone), 613-941-3537 (fax), sche-ann@hc-sc.gc.ca (email).

PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1) ([see footnote a](#)) of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1433 — Neotame)*.

Interested persons may make representations concerning the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Ronald Burke, Director, Bureau of Food Regulatory, International and Interagency Affairs, Department of Health, Room 2395, 200 Tunney's Pasture Driveway, Address Locator 0702C1, Tunney's Pasture, Ottawa, Ontario K1A 0L2 (tel.: 613-957-1828; fax: 613-941-3537; email: sche-ann@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, December 7, 2006

MARY O'NEILL
Assistant Clerk of the Privy Council

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1433 —

NEOTAME)

AMENDMENTS

1. Subsection B.01.015(2) of the *Food and Drug Regulations* ([see footnote 1](#)) is repealed.

2. Subsection B.01.017(2) of the Regulations is repealed.

3. Subsection B.01.020(2) of the Regulations is repealed.

4. The Regulations are amended by adding the following after section B.01.022:

B.01.023. The label of a food, other than a table-top sweetener, that contains neotame shall carry the following information:

(a) subject to paragraph (b), a statement on the principal display panel to the effect that the food contains neotame or is sweetened with neotame, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

(b) in the case where other sweeteners or sweetening agents are used in conjunction with neotame, a statement on the principal display panel, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*, to the effect that the food

(i) contains neotame and (naming the other sweeteners and the sweetening agents), or

(ii) is sweetened with neotame and (naming the other sweeteners and the sweetening agents);

(c) if the label of the food carries a nutrition facts table, a statement setting out the neotame content expressed in milligrams per serving of stated size; and

(d) if the label of the food does not carry a nutrition facts table, a statement setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence on any part of the label:

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the neotame content, expressed in milligrams.

B.01.024. The label of a food that is a table-top sweetener that contains neotame shall carry the following information:

(a) a statement on the principal display panel to the effect that the food contains neotame or is sweetened with neotame, in letters of at least the same size and prominence as the letters used for showing the numerical quantity in the declaration of net quantity as required under section 14 of the *Consumer Packaging and Labelling Regulations*;

(b) a statement on any part of the label of the sweetness per serving expressed in terms of the amount of sugar required to produce an equivalent degree of sweetness;

(c) if the label of the food carries a nutrition facts table, a statement setting out the neotame content expressed in milligrams per serving of stated size; and

(d) if the label of the food does not carry a nutrition facts table, a statement setting out the following energy value and contents of the food, per serving of stated size, grouped together and given equal prominence on any part of the label:

(i) the energy value, expressed in Calories (Calories or Cal) and kilojoules (kilojoules or kJ),

(ii) the protein, fat and carbohydrate content, expressed in grams, and

(iii) the neotame content, expressed in milligrams.

5. Paragraph B.01.401(3)(c) of the Regulations is replaced by the following:

(c) the product contains added acesulfame-potassium, aspartame, neotame or sucralose;

6. The portion of item 2 of the table following section B.01.513 of the Regulations in column 2 is amended by striking out the word "or" at the end of paragraph (a), by adding the word "or" at the end of paragraph (b) and by adding the following after paragraph (b):

	Column 2
Item	Conditions — Food
2.	(c) 2 Calories or 8 kilojoules or less for an amount of the food that is equivalent in sweetness to 4 g of sugar, if the food is a table-top sweetener.

7. Table IX to section B.16.100 of the Regulations is amended by adding the following after item M.3:

	Column I	Column II	Column III
Item No.	Additive	Permitted in or on	Maximum Level of Use

N.1	Neotame	(1) Table-top sweeteners	(1) Good Manufacturing Practice
		(2) Breakfast cereals	(2) 0.016%
		(3) Beverage mixes; Unstandardized beverages; Unstandardized beverage concentrates	(3) 0.003% in beverages as consumed
		(4) Dessert mixes; Fillings; Filling mixes; Toppings; Topping mixes; Unstandardized desserts; Yogurt	(4) 0.01% in products as consumed
		(5) Breath freshener products; Chewing gum	(5) 0.032%
		(6) Unstandardized fruit spreads; Unstandardized purées and sauces; Unstandardized table syrups	(6) 0.007%
		(7) Peanut and other nut spreads; Unstandardized salad dressings	(7) 0.002%
		(8) Unstandardized condiments	(8) 0.007%
		(9) Confectionary glazes for snack foods; Sweetened seasonings or coating mixes for snack foods	(9) 0.0032%
		(10) Unstandardized confections and their coatings	(10) 0.01%
		(11) Unstandardized bakery products and baking mixes	(11) 0.013% in products as consumed

COMING INTO FORCE

8. These Regulations come into force on the day on which they are registered.

[50-1-o]

[Footnote a](#)

S.C. 1999, c. 33, s. 347

[Footnote 1](#)

C.R.C., c. 870

NOTICE:

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.

 [Top of page](#)

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