



Health
Canada

Santé
Canada

Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of beta-Amylase from *Priestia flexa* AE-BAF in Glutinous Rice-based Cakes

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0199

March 28, 2023



Canada 

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (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 the Canada.ca website. A petitioner can request that Health Canada authorize a new additive, or a new source or a new condition of use for an already permitted food additive, by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket authorization 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's Food Directorate received a food additive submission seeking authorization for the use of beta-amylase (β -amylase) from *Bacillus flexus* AE-BAF as a food enzyme in mochi and dango.¹ The requested maximum level of use for this food enzyme is Good Manufacturing Practice.

β -amylase from *B. flexus* AE-BAF is already permitted for use in bread, flour, whole wheat flour, brewers' mash, starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or maltose, and unstandardized bakery products. This submission is a request to extend the use of this enzyme from this already-permitted source to mochi and dango.

The results of the Food Directorate's evaluation of available scientific data support the safety and efficacy of β -amylase from *B. flexus* AE-BAF when used as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to enable the use of β -amylase from *B. flexus* AE-BAF by adding the entry shown in the table below in Columns 3 and 4 of item A.1(i) to the list (**bold** font not used in the list). For the definition of "Good Manufacturing Practice" set out in column 4 as a Maximum Level of Use, see the [Marketing Authorization for Food Additives That May Be Used as Food Enzymes](#).

Modification to the *List of Permitted Food Enzymes*:

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
A.1	(i) β -amylase	<i>Priestia flexa</i> AE-BAF (previous name: <i>Bacillus flexus</i> AE-BAF)	(5) Glutinous rice-based cakes	(5) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of β -amylase from *B. flexus* AE-BAF for use as food enzyme in mochi and dango. The Directorate concluded that information related to allergenicity, chemistry, microbiology, molecular biology, nutrition, and toxicology supports the

¹ Mochi was described as a type of Japanese rice cake made by pounding and kneading steamed rice, and dango as a type of Japanese rice cake made by steaming or boiling a mixture of water and rice flour that has been kneaded and rolled.

safety of β -amylase from *B. flexus* AE-BAF for its requested uses and technical information indicates the enzyme is effective for its intended purposes. Therefore, Health Canada has enabled the requested uses of β -amylase from *B. flexus* AE-BAF by adding to the [List of Permitted Food Enzymes](#) the new entry shown in the above table.

Other Relevant Information

Food additives such as β -amylase are required to meet food-grade specifications set out in Part B of the Regulations, where such specifications exist, or those set out in the most recent edition of the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications* where there are no specifications in Part B. The *Food Chemicals Codex* is a compendium of food-grade specifications for food ingredients, including food additives, published by the United States Pharmacopeial Convention. Specifications in the *Combined Compendium of Food Additive Specifications* and its associated *General Specifications and Considerations for Enzyme Preparations* are prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), both of which are published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force **March 28, 2023**, the day it was published in [List of Permitted Food Enzymes](#).

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. Anyone wishing to submit an inquiry or new scientific information on the use of a permitted additive may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically about beta-amylase from *B. flexus* AE-BAF, please use the words "**beta-amylase (NOM-0199)**" 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 0K9

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