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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of β -amylase from *Bacillus flexus* AE-BAF in Various Foods

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0161

February 9, 2021



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 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's Food Directorate received a food additive submission seeking approval for the use of β -amylase from *Bacillus flexus* AE-BAF as a food enzyme in various foods: brewers' mash used in the production of ale, beer, light beer, malt liquor, porter, stout; bread, flour, whole wheat flour; starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or maltose; and unstandardized bakery products. The food enzyme is intended to be used at a level consistent with Good Manufacturing Practice.

β -amylase is a subtype of amylase and barley malt is a permitted source of this enzyme. β -amylase from barley malt is already permitted for use in Canada as a food enzyme in the manufacture of all the foods of interest to the petitioner other than brewers' mash.

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 set out in the table below. 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 a new entry "(i) β -amylase" to column 1 for Item No. A.1 and adding the entries in columns 2, 3 and 4 shown below to the new entry (i) of Item No. A.1 in the List.

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>Bacillus flexus</i> AE-BAF	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
			(2) Brewers' Mash	(2) Good Manufacturing Practice
			(3) Starch used in the production of dextrins, dextrose, glucose (glucose syrup), glucose solids (dried glucose syrup) or maltose	(3) Good Manufacturing Practice
			(4) Unstandardized bakery products	(4) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of β -amylase from *B. flexus* AE-BAF for use as a food enzyme. The assessment concluded that information related to allergenicity, chemistry, microbiology, molecular biology, nutrition, and toxicology supports the safety of β -amylase from *B. flexus* AE-BAF for its requested uses. Therefore, the Department has enabled the requested uses of β -amylase from *B. flexus* AE-BAF by adding to the [List of Permitted Food Enzymes](#) the new entries shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as β -amylase that do not have food-grade specifications set out in Part B of the Regulations meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications*. The *Food Chemicals Codex* is a compendium of standards for purity and identity for food ingredients, including food additives, published by the United States Pharmacopeial Convention. 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) and published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force **February 9, 2021**, the day it was published in the [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, including β -amylase from *B. flexus* AE-BAF. Anyone wishing to submit new scientific information on the use of this additive 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 words " **β -amylase (NOM-0161)**" 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: hc.bcs-bipc.sc@canada.ca