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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of alpha-Amylase from *Bacillus subtilis* AR-651 in Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0200

April 27, 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 alpha-amylase (α -amylase) from *Bacillus subtilis* AR-651 in bread, flour, whole wheat flour, and unstandardized bakery products. The requested maximum level of use for this food enzyme is Good Manufacturing Practice.

α -Amylase from other sources is already permitted for use in the foods requested by the petitioner. However, *B. subtilis* AR-651 was not a permitted source organism for any food enzyme in Canada.

The results of the Food Directorate's evaluation of available scientific data support the safety of α -amylase from *B. subtilis* AR-651 when used as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to enable the use of α -amylase from *B. subtilis* AR-651 by adding this new source organism in Column 2 of Item A.1 in the list, as shown in the table below (in bold font in this Notice to illustrate the change). 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*

The new entry shown below in column 2 (bold font not used in the List), was added 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	Amylase	Bacillus subtilis NBA (DS 68703); Bacillus subtilis AR-651	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
			(2) Unstandardized bakery products	(2) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of α -amylase from *B. subtilis* AR-651 for use as a food enzyme in bread, flour, whole wheat flour and unstandardized bakery products. The Directorate considered allergenicity, chemistry, microbiology, molecular biology, nutrition, and toxicology in the assessment. The results of the assessment support the safety of α -amylase from *B. subtilis* AR-651 for its

requested uses. Therefore, Health Canada has enabled the requested uses of α -amylase from *B. subtilis* AR-651 by adding to the [List of Permitted Food Enzymes](#) the new entry shown in the above table.

Other Relevant Information

Food additives such as α -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*. 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 **April 27, 2023**, 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. Anyone wishing to submit an inquiry or new scientific information on the use of a permitted food additive may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically about α -amylase from *B. subtilis* AR-651, please use the words "**alpha-amylase (NOM-0200)**" in the subject line of your e-mail.

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