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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Maltogenic *alpha*-Amylase from *Bacillus licheniformis* MDT06-221 in Bread, Flour, Whole Wheat Flour, Unstandardized Bakery Products and Pasta

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0127]

February 26, 2019

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

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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 maltogenic *alpha*-amylase from *Bacillus licheniformis* MDT06-221 in bread; flour; whole wheat flour; unstandardized bakery products such as buns, cakes, and tortillas; and pasta¹ and noodles. The food enzyme is intended to be used at a level of use consistent with Good Manufacturing Practice (GMP). The purpose for using the maltogenic *alpha*-amylase in the flour, whole wheat flour, bread, and unstandardized bakery products is to soften the bakery product, improve the elasticity and resilience of the dough, and provide an anti-staling effect. The purpose for using the maltogenic *alpha*-amylase in noodles is to prevent clumping of cooked noodles and improve texture.

Maltogenic *alpha*-amylase is already permitted for use in Canada as a food enzyme in bread, flour, whole wheat flour and unstandardized bakery products. However, *B. licheniformis* MDT06-221 has not previously been a permitted enzyme source.

The results of the Food Directorate's evaluation of available scientific data support the safety of maltogenic *alpha*-amylase from *B. licheniformis* MDT06-221 when used as set out in the table below. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of maltogenic *alpha*-amylase, which is identified in the List as "Amylase (maltogenic)", from *B. licheniformis* MDT06-221 by adding entries to columns 2, 3, and 4 of the existing listing for Amylase (maltogenic), as shown below.

¹ Although the food additive submission requested the use of maltogenic *alpha*-amylase in both pasta and noodles, pasta is considered a synonym for "alimentary paste", as described in Division 13, Section B, of the Regulations. Pasta (alimentary paste) includes noodles, macaroni, spaghetti, etc.

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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.2	Amylase (maltogenic)	<i>Bacillus licheniformis</i> MDT06-221	(1) Bread; Flour; Whole Wheat Flour	(1) Good Manufacturing Practice
			(2) Pasta	(2) Good Manufacturing Practice
			(3) Unstandardized bakery products	(3) Good Manufacturing Practice

Corrective Modification

A corrective modification has been made to item G.1, Glucoamylase, in the *List of Permitted Food Enzymes*. “Maltase” was identified in Column 1 as a synonym for glucoamylase. However, the synonym should have been identified as “acid maltase”. This has been corrected.

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of the requested uses of maltogenic *alpha*-amylase from *B. licheniformis* MDT06-221. The assessment concluded that information related to chemistry, microbiology, molecular biology, nutrition, and toxicology supports the safety of maltogenic *alpha*-amylase from *B. licheniformis* for its requested uses. Therefore, the Department has enabled the requested uses of amylase (maltogenic) from *B. licheniformis* MDT06-221 by modifying the *List of Permitted Food Enzymes* as shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as maltogenic *alpha*-amylase that do not have food-grade specifications set out in Part B of the Regulations meet the most recent food-grade specifications set out in 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 both prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and published by the Food and Agriculture Organization of the United Nations.

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Implementation and Enforcement

The above modification came into force **February 26, 2019**, 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 any new scientific information on the safety in use of any food additive, including maltogenic *alpha*-amylase from *B. licheniformis* MDT06-221. 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 "**Maltogenic *alpha*-amylase (NOM -0127)**" in the subject line of your e-mail.

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