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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Maltogenic α -Amylase from Three Sources in Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0175

October 25, 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 three food additive submissions seeking approval for the use of maltogenic *alpha*- (α -) amylase from *Bacillus licheniformis* HyGe750n6, *B. subtilis* RF13018, and *Saccharomyces cerevisiae* M17906 in bread, flour, whole wheat flour, and unstandardized bakery products. This food enzyme is intended to be used at a maximum level consistent with Good Manufacturing Practice.¹ The purpose of using maltogenic α -amylase is to delay the staling of baked goods.

Maltogenic α -amylase from other sources is already permitted in the same foods of interest to the petitioners. The new source organisms, *B. licheniformis* HyGe750n6, *B. subtilis* RF13018, and *S. cerevisiae* M17906, were not permitted sources for any food enzyme in Canada.

The results of the Food Directorate's evaluation of available scientific data support the safety of maltogenic α -amylase from *B. licheniformis* HyGe750n6, *B. subtilis* RF13018, and *S. cerevisiae* M17906 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 amylase (specifically, maltogenic α -amylase) to include this enzyme from these three sources by adding a new entry "(i) α -Amylase (maltogenic)" to column 1 of Item A.2 and adding the entries in columns 2, 3 and 4 shown below to the new entry (i) of Item No. A.2 in the List.

Consequential Modification

The previous list entries for maltogenic amylase from *B. licheniformis* MDT06-221, *B. subtilis* BS154, and *B. subtilis* RF12029 did not specify the *alpha* configuration of this enzyme.² Since the List is modified to include a new separate subitem A.2(i) specifically for maltogenic α -amylase, the sources *B. subtilis* BS154 and *B. subtilis* RF12029 were removed from their previous list entry for maltogenic amylase and grouped by alphabetical order with the new sources *B. licheniformis* HyGe750n6, *B. subtilis* RF13018 and *S. cerevisiae* M17906 under new subitem A.2(i) for maltogenic α -amylase in the [List of Permitted Food Enzymes](#), as shown below. A separate entry was created under subitem A.2(i) of this List for the source *B. licheniformis* MDT06-221, as shown below, because maltogenic α -amylase from this source, but not the other sources, is also listed for use in pasta.

¹ See the definition of Good Manufacturing Practice in the [Marketing Authorization for Food Additives That May Be Used as Food Enzymes](#).

² The sources *B. subtilis* BS154, *B. subtilis* RF12029 and *B. licheniformis* MDT06-221 were previously listed under item A.2 Amylase (maltogenic) the day before the modification for *B. licheniformis* HyGe750n6, *B. subtilis* RF13018 and *S. cerevisiae* M17906, which is the subject of the present NOM, was made.

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 | (i) α -Amylase (maltogenic) | <i>Bacillus licheniformis</i> HyGe750n6; <i>Bacillus subtilis</i> BS154; <i>Bacillus subtilis</i> RF12029; <i>Bacillus subtilis</i> RF13018; <i>Saccharomyces cerevisiae</i> M17906 | (1) Bread; Flour; Whole wheat flour | (1) Good manufacturing practice |
| | | | (2) Unstandardized bakery products | (2) Good manufacturing practice |
| | | <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 |

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of maltogenic α -amylase from each of *B. licheniformis* HyGe750n6, *B. subtilis* RF13018, and *S. cerevisiae* M17906, for use as a food enzyme in the foods of interest to the petitioners. The Department concluded that information related to allergenicity, chemistry, microbiology, molecular biology, and toxicology supports the safety of maltogenic α -amylase from these sources for its requested uses, and technical information indicates the enzyme is effective for its intended purpose. Therefore, the Department has enabled the requested uses of maltogenic α -amylase from *B. licheniformis* HyGe750n6, *B. subtilis* RF13018, and *S. cerevisiae* M17906 by adding to the [List of Permitted Food Enzymes](#) the new entries shown in the above table.

Other Relevant Information

Food additives such as maltogenic α -amylase are required to meet food-grade specifications set out in Part B of the Regulations 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 standards for purity and identity 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 **October 25, 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 maltogenic α -amylase from *B. licheniformis* HyGe750n6, *B. subtilis* RF13018, and *S. cerevisiae* M17906. Anyone wishing to submit an inquiry or new scientific information on the use of this additive may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**alpha-amylase maltogenic (NOM-0175)**" in the subject line of your e-mail.

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