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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Glutaminase from *Bacillus licheniformis* SJ13263 in Various Foods

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0174

October 4, 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 glutaminase from *Bacillus licheniformis* SJ13263 as a food enzyme in bread; dairy-based flavouring preparation; flour; hydrolyzed animal, milk and vegetable protein; pasta; unstandardized bakery products; whole wheat flour; and yeast extract. This food enzyme is intended to be used at a maximum level consistent with Good Manufacturing Practice¹. The petitioner indicated that the use of glutaminase in baking and other cereal-based processes serves to produce a dough that is more extensible² and easier to handle. In the manufacture of hydrolyzed animal, milk and vegetable protein, dairy-based flavouring preparations and yeast extract, the petitioner explained that glutaminase serves to increase levels of glutamate in order to enhance flavour (i.e. enhance umami flavor, similar to the flavor achieved by using monosodium glutamate (MSG)) in the final foods to which these ingredients are added.

Glutaminase from another microbial source is already permitted for use in certain foods requested by the petitioner. Although *B. licheniformis* and numerous strains of this bacterium are permitted sources for several food enzymes other than glutaminase, the specific strain of *B. licheniformis*, SJ13263, is a new source for a food enzyme in Canada.

The results of the Food Directorate's evaluation of available scientific data support the safety of glutaminase from *B. licheniformis* SJ13263 when used as set out in the table below. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to enable the requested uses of glutaminase from *B. licheniformis* SJ13263 by adding the entry shown below to 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
G.5	Glutaminase	<i>Bacillus licheniformis</i> SJ13263	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
			(2) Dairy-based flavouring	(2) Good Manufacturing Practice

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

² The petitioner has defined the "extensibility" as the degree to which a dough can be stretched without tearing.

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
			preparations	
			(3) Hydrolyzed animal, milk and vegetable protein	(3) Good Manufacturing Practice
			(4) Pasta	(4) Good Manufacturing Practice
			(5) Unstandardized bakery products	(5) Good Manufacturing Practice
			(6) Yeast extract	(6) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of glutaminase from *B. licheniformis* SJ13263 for use as a food enzyme in the foods of interest to the petitioner. The Department concluded that information related to allergenicity, chemistry, microbiology, molecular biology, and toxicology supports the safety of glutaminase from *B. licheniformis* SJ13263 for its requested uses, and technical information indicates the enzyme is effective for its intended purposes. Therefore, the Department has enabled the requested uses of glutaminase from *B. licheniformis* SJ13263 by adding to the [List of Permitted Food Enzymes](#) the new entry shown in the above table.

Other Relevant Information

Glutaminase will increase the free glutamic acid content of the foods it is added to. When glutamic acid or its salts (e.g. MSG) or hydrolyzed plant protein are added to a prepackaged food, they must be declared in the list of ingredients on the food label, even if they are a component of a preparation or mixture such as flavouring preparation or seasoning mixture that is usually exempt from component declaration (this requirement is set out in section B.01.009 of the Regulations). This labeling is not required for other food ingredients or foods that contain free glutamate.

Food additives such as glutaminase from *B. licheniformis* SJ13263 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 4, 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 glutaminase from *B. licheniformis* SJ13263. 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 "**glutaminase (NOM-0174)**" in the subject line of your e-mail.

[Bureau of Chemical Safety, Food Directorate](#)

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