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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of the Enzyme Asparaginase, from *Bacillus subtilis* MOL2940, in Bread, Flour, Whole Wheat Flour, Unstandardized Foods and Green Coffee

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0050]

May 21, 2015

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch





Canada

Summary

Food additives are regulated in Canada under Marketing Authorizations (MAs) issued by the Minister of Health and the *Food and Drug 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 MA's and published on Health Canada's 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 received a food additive submission seeking approval for the use of the enzyme asparaginase, obtained from *Bacillus subtilis* MOL2940, in bread, flour, whole wheat flour, unstandardized foods and green coffee. Asparaginase is used in food applications to reduce the amount of acrylamide that can be formed during cooking or heat processing from the amino acid asparagine that is naturally present in food. Asparaginase from other microbial sources is already permitted for use in the same foods. Information in the submission indicated that asparaginase from *B. subtilis* MOL2940 is advantageous, compared to asparaginase from other permitted sources, as it functions at a higher optimal temperature thus making the enzyme more useful in foods that are baked at higher temperatures.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of asparaginase from this source organism when used as described in the requested foods. Therefore, Health Canada has modified the *List of Permitted Food Enzymes* to extend the permitted sources of asparaginase to a new source organism, *B. subtilis* MOL2940 by adding the following entry to the list:

Modification to the *List of Permitted Food Enzymes*

Item No.	Additive	Permitted Source	Permitted in or upon	Maximum Level of Use and Other Conditions
A.3	Asparaginase	*Bacillus subtilis* MOL2940	(1) Bread; Flour; Whole wheat flour (2) Unstandardized foods (3) Green Coffee	(1) Good Manufacturing Practice (2) Good Manufacturing Practice (3) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate has completed a pre-market safety and efficacy assessment of asparaginase obtained from *B. subtilis* MOL2940. The assessment considered microbiological, toxicological and technical aspects of this food additive when used as described in the table above.

The Food Directorate reviewed specifications related to the microbiological safety of the enzyme preparation and data demonstrating compliance with these specifications. The Directorate also conducted a toxicological evaluation based on a conservative estimated intake of the enzyme preparation from its proposed use in the requested foods.

Based on the results of the safety assessment, Health Canada considers that the data demonstrate the safety in use of asparaginase obtained from *B. subtilis* MOL2940, at a maximum level of use consistent with good manufacturing practice (GMP), in bread, flour, whole wheat flour, unstandardized foods and green coffee. The Department has therefore enabled the use of asparaginase obtained from this source organism as described in the above table.

Other Relevant Information

Acrylamide is a chemical formed in a reaction between asparagine and reducing sugars when food products are heated to temperatures above 120 ^{o}C. Both asparagine and reducing sugars are commonly found in many raw food materials.

Health Canada has identified dietary exposure to acrylamide as a potential human health concern and therefore is supportive of efforts by industry to find ways to reduce acrylamide in foods. Enabling the use of asparaginase obtained from *B. subtilis* MOL2940 will provide an additional option for reducing acrylamide formation in food, especially in foods that require higher baking temperatures during manufacture (e.g., breakfast cereals).

All enzymes used as food additives, including asparaginase, must meet the specifications for enzyme preparations set out in the most recent edition of the *Food Chemicals Codex*, a compendium of standards for the purity and identity of food ingredients, including food additives, which is published by United States Pharmacopeial Convention.

Implementation and Enforcement

The above modification came into force **May 21, 2015**, 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 permitted food additive including asparaginase from *Bacillus subtilis* MOL2940. 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 "**asparaginase from *Bacillus subtilis* MOL2940**" 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 0L2
E-mail: bcs-bipc@hc-sc.gc.ca