



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Asparaginase Obtained from *Aspergillus niger* AGN7-41 as a Food Enzyme in Bread, Flour, Whole Wheat Flour, and Unstandardized Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0023]

January 21, 2014

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Asparaginase Obtained from *Aspergillus niger* AGN7-41 as a Food Enzyme in Bread, Flour, Whole Wheat Flour, and Unstandardized Foods

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 MAs. 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 asparaginase obtained from *Aspergillus niger* AGN7-41 as a food enzyme at a maximum level of use in accordance with good manufacturing practice in bread, flour, whole wheat flour, and unstandardized foods. The purpose of using asparaginase in these products is to reduce the formation of acrylamide.

Asparaginase, when obtained from another strain of *Aspergillus niger* (*A. niger* ASP72), is already permitted for use in Canada as a food enzyme in bread, flour, whole wheat flour and unstandardized foods.

The results of Health Canada's evaluation of available scientific data support the safety of asparaginase obtained from *A. niger* AGN7-41 when used as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of asparaginase 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
A.3	Asparaginase	<i>Aspergillus niger</i> AGN7-41	(1) Bread; Flour; Whole wheat flour (2) Unstandardized foods	(1) Good Manufacturing Practice (2) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a pre-market safety assessment of asparaginase obtained from *A. niger* AGN7-41. The assessment considered microbiological, toxicological, nutritional and technical aspects of asparaginase obtained from *A. niger* AGN7-41 when used as requested in the food additive submission.

Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of asparaginase obtained from *A. niger* AGN7-41 when used under the conditions evaluated. The Department has therefore enabled the use of asparaginase obtained from *A. niger* AGN7-41 as described in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that all food enzymes, including asparaginase, used as food additives meet the specifications for enzyme preparations set out in the most recent edition of the *Food Chemicals Codex* (FCC). The FCC is a compendium of standards for purity and identity of food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

Implementation and Enforcement

The above modification came into force January 21, 2014, 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 asparaginase. 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**" 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: bc-s-bipc@hc-sc.gc.ca