



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 the Enzyme Asparaginase, Obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10), in Green Coffee

Document Reference Number: [NOM/ADM-0007]

March 25, 2013

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 the Enzyme Asparaginase, Obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10), in Green Coffee

Summary

Food additives are regulated in Canada under the *Food and Drug Regulations* and [Marketing Authorizations](#) (MAs) issued by the Minister of Health. 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 the enzyme asparaginase, obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10), at a maximum level of use consistent with Good Manufacturing Practice (GMP) in green coffee beans.

Asparaginase obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10) is already permitted for use as an enzyme in bread, flour, whole wheat flour and unstandardized foods.

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 green coffee. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of asparaginase obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10) to green coffee by adding the following entry 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 oryzae</i> (pCaHj621/BECh2#10)	(3) Green Coffee	(3) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate has completed a pre-market safety and efficacy assessment of the enzyme asparaginase obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10). The assessment considered microbiological, toxicological and technical aspects of asparaginase obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10) when used as described in the table above.

Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of the Enzyme Asparaginase, Obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10), in Green Coffee

Asparaginase obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10) is the same enzyme that is already permitted for use in bread, flour, whole wheat flour and unstandardized foods according to the *List of Permitted Food Enzymes*. 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 green coffee in addition to its already permitted uses.

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 °C. Both asparagine and reducing sugars are natural constituents of many raw food materials, including green coffee beans.
- Health Canada has identified dietary exposure to acrylamide as a potential human health concern. In 2012, based on the results of its Acrylamide Monitoring Program, the Food Directorate published an updated assessment of [dietary exposure to acrylamide](#) in Canada in which it identified coffee (ready-to-drink) as one of the top contributors to average total dietary acrylamide exposure.
- The Food Directorate is supportive of efforts by industry to find ways to reduce acrylamide in foods. Enabling the use of asparaginase obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10) in green coffee will provide an additional option for reducing acrylamide formation during the roasting of coffee beans which, in turn, could potentially reduce the acrylamide content of coffee as consumed.
- 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.
- There is a standard of identity for green coffee set out in section B.05.001 of Division 5 of the *Food and Drug Regulations* (Part B). Since green coffee is a standardized food in Canada, Health Canada consulted with the Canadian Food Inspection Agency and with the appropriate industry association about the proposed use of asparaginase in coffee. No objections were received.

Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data demonstrate the safety in use of asparaginase obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10), at a maximum level of use consistent with GMP, in green coffee. The Department has therefore enabled the use of asparaginase obtained from this source organism as described in the above table.

Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of the Enzyme Asparaginase, Obtained from *Aspergillus oryzae* (pCaHj621/BECh2#10), in Green Coffee

Implementation and Enforcement

The above modification came into force March 25, 2013, 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 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 green coffee**" in the subject line of your e-mail

Bureau of Chemical Safety
251 Sir Frederick Banting Driveway
Tunney's Pasture, PL: 2202C
Ottawa, Ontario K1A 0L2
E-mail: bcs-bipc@hc-sc.gc.ca