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 Protein-glutaminase from *Chryseobacterium proteolyticum* AE-PG in Various Standardized and Unstandardized Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: NOM/ADM-0130

March 18, 2019

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* (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 the enzyme protein-glutaminase from *Chryseobacterium proteolyticum* AE-PG in various standardized and unstandardized foods. The food enzyme is intended to be used at a level consistent with Good Manufacturing Practice.

The results of the Food Directorate's evaluation of available scientific data support the safety and efficacy of protein-glutaminase from *C. proteolyticum* AE-PG when used as set out in the table below. Since this is a food additive that was not previously permitted for use in Canada, Health Canada published a *Notice of Health Canada's Proposal to Enable the Use of Protein-glutaminase from Chryseobacterium proteolyticum AE-PG as a Food Enzyme in Various Standardized and Unstandardized Foods* [NOP/ADP-0030] on October 10, 2018, which was open to the public for comment for 75 days. No new scientific information was submitted to the Department as a result of this Notice of Proposal. Since the conclusions of the evaluation remain as described in the publication, Health Canada has enabled the requested uses of protein-glutaminase from *C. proteolyticum* AE-PG by adding the entries shown in the table below to the *List of Permitted Food Enzymes*.

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
P.6.1	Protein-glutaminase	*Chryseobacterium proteolyticum* AE-PG	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
			(2) Hydrolyzed animal, milk and vegetable protein	(2) Good Manufacturing Practice
			(3) Pasta	(3) Good Manufacturing Practice

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
			(4) Plant-based beverages	(4) Good Manufacturing Practice
			(5) Unstandardized bakery products	(5) Good Manufacturing Practice
			(6) Unstandardized dairy products	(6) Good Manufacturing Practice
			(7) Yeast extract	(7) Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of protein-glutaminase from *C. proteolyticum* AE-PG for use as a food enzyme. The assessment concluded that information related to chemistry, microbiology, nutrition, toxicology, and allergenicity supports the safety of protein-glutaminase from *C. proteolyticum* AE-PG for its requested uses. Therefore, the Department has enabled the requested uses of protein-glutaminase from *C. proteolyticum* AE-PG by adding to the *List of Permitted Food Enzymes* the new item number and its corresponding entries shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as protein-glutaminase that do not have food-grade specifications set out in Part B of the Regulations meet the most recent food-grade specifications set out in 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. The *Combined Compendium of Food Additive Specifications* and its associated *General Specifications and Considerations for Enzyme Preparations* are both prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and published by the Food and Agriculture Organization of the United Nations.

Notification – Summary of Comments

No comments were received in response to *Health Canada's Proposal to Enable the Use of Protein-glutaminase from Chryseobacterium proteolyticum AE-PG as a Food Enzyme in Various Standardized and Unstandardized Foods*, published on October 10, 2018.

Implementation and Enforcement

The above modification came into force **March 18, 2019**, 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 protein-glutaminase from *C. proteolyticum* AE-PG. 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 "**protein-glutaminase (NOM-0130)**" 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: hc.bcs-bipc.sc@canada.ca