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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Protease from *Geobacillus stearothermophilus* TP7 as an Enzyme in Hydrolyzed Animal, Milk, and Vegetable Protein, and in Hydrolyzed Yeast

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0077]

July 14, 2016

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 MAs 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 protease from *Geobacillus stearothermophilus* TP7 as a food enzyme at a maximum level of use in accordance with good manufacturing practice (GMP) in hydrolyzed animal, milk, and vegetable protein, and in hydrolyzed yeast. Protease from various other source organisms is already permitted for use in Canada as a food enzyme in a range of foods, including hydrolyzed animal, milk and vegetable protein. However, *Geobacillus stearothermophilus* TP7 has not previously been approved in Canada as a permitted source for any enzyme.

The results of Health Canada’s evaluation of available scientific data support the safety and efficacy of protease from *G. stearothermophilus* TP7 when used as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of protease by adding the entry shown below to the list.

Modifications 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	Protease	<i>Geobacillus stearothermophilus</i> TP7	(1) Hydrolyzed animal, milk and vegetable protein	(1) Good Manufacturing Practice
			(2) Hydrolyzed yeast	(2) Good Manufacturing Practice

Justification

Health Canada's Food Directorate completed a pre-market safety assessment of the requested uses of protease from *G. stearothermophilus* TP7. The assessment considered microbiological, toxicological, and chemical aspects of this additive, and found that the requested uses are acceptable from a food safety perspective. Therefore, the Department has enabled the requested uses of protease from *G. stearothermophilus* TP7 by modifying the *List of Permitted Food Enzymes* as described in the above table.

Implementation and Enforcement

The above modification came into force **July 14, 2016**, 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 **protease from *Geobacillus stearothermophilus* TP7**. 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 "**protease from *Geobacillus stearothermophilus* TP7**" in the subject line of your e-mail.

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