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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Protease from *Trichoderma reesei* RF8963 in Hydrolyzed Animal, Milk and Vegetable Protein

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0150

August 27, 2020



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 protease (i.e., serine protease) from *Trichoderma reesei* RF8963 in hydrolyzed animal, milk and vegetable protein. The food enzyme is intended to be used at a level consistent with Good Manufacturing Practice.

Proteases from sources other than *T. reesei* are already permitted for use in Canada in various foods, including hydrolyzed animal, milk and vegetable protein.

The results of the Food Directorate's evaluation of available scientific data support the safety of protease from *T. reesei* RF8963 when used as set out in the table below. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of protease from *T. reesei* RF8963 by adding the entry shown in the table below.

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	Protease	<i>Trichoderma reesei</i> RF8963	Hydrolyzed animal, milk and vegetable protein	Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of protease from *T. reesei* RF8963 in hydrolyzed animal, milk and vegetable protein. The assessment concluded that information related to chemistry, microbiology, molecular biology, nutrition, toxicology and allergenicity supports the safety of protease from *T. reesei* RF8963 for its requested use. Therefore, the Department has enabled the requested use of protease from *T. reesei* RF8963 by adding to the [List of Permitted Food Enzymes](#) the new entry shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as protease that do not have food-grade specifications set out in Part B of the Regulations meet the food-grade specifications set out in the most recent edition of 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 prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force **August 27, 2020**, the day it was published in [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 *T. reesei* RF8963. 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 (NOM-0150)**" in the subject line of your e-mail.

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