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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Acid Prolyl Endopeptidase from *Aspergillus niger* GEP in Certain Foods

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0155

October 9, 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 the enzyme acid prolyl endopeptidase (a type of protease) from *Aspergillus niger* GEP in brewers' mash; ale, beer, light beer, malt liquor, porter, and stout; distiller's mash, and protein hydrolysates (hydrolyzed animal, milk and vegetable protein). In addition, the use of this enzyme from this source was also requested in cereal- and plant-derived ingredients which will be further used as ingredients in the manufacture of non-alcoholic plant-based beverages. As with all food enzymes, the proposed uses described above are intended to be used at a level consistent with Good Manufacturing Practice.

Protease from other sources is already permitted for use in Canada as a food enzyme in the same foods that the petitioner has requested, with the exception of brewers' mash. However, the GEP strain of *Aspergillus niger*, which expresses the protease "acid prolyl endopeptidase", is not a permitted source organism for any food enzyme in Canada.

The results of the Food Directorate's evaluation of available scientific data support the safety of acid prolyl endopeptidase from *A. niger* GEP for use as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of protease (specifically, the protease "acid prolyl endopeptidase") by adding a new entry "(i) acid prolyl endopeptidase" to column 1 for Item No. P.6 and adding the entries in columns 2, 3 and 4 shown below to the new entry (i) of Item No. P.6 in 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
P.6	Protease (i) Acid prolyl endopeptidase	<i>Aspergillus niger</i> GEP	(1) Beer	(1) Good Manufacturing Practice
			(2) Brewers' mash	(2) Good Manufacturing Practice
			(3) Distillers' mash	(3) Good Manufacturing Practice
			(4) Hydrolyzed animal, milk and vegetable protein	(4) 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
			(5) Plant-based beverages	(5) Good Manufacturing Practice

Ale, malt liquor, porter and stout are not individually listed because these beverages, which formerly had their own standards, are now included in the recently amended standard for beer ([B.02.130](#)). Therefore, the entry for “Beer” includes ale, malt liquor, porter and stout.

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of the protease acid prolyl endopeptidase from *A. niger* GEP for use as a food enzyme. The assessment concluded that information related to allergenicity, chemistry, microbiology, molecular biology, nutrition, and toxicology supports the safety of this food enzyme from this source for its requested uses. Therefore, the Department has enabled the requested uses of acid prolyl endopeptidase from *A. niger* GEP by adding to the [List of Permitted Food Enzymes](#) the new entries as shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as the food enzyme acid prolyl endopeptidase 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 **October 9, 2020**, 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 acid prolyl endopeptidase from *A. niger* GEP. 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 "**acid prolyl endopeptidase (NOM-0155)**" in the subject line of your e-mail.

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