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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Pectinase from *Aspergillus niger* in Unstandardized Fruit and Vegetable Products

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0157

January 5, 2021



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 pectinase from *Aspergillus niger* as a food enzyme in unstandardized fruit and vegetable products. The food enzyme is intended to be used at a level consistent with Good Manufacturing Practice.

Pectinase from *A. niger* is already permitted for use in Canada as a food enzyme in several foods, including certain unstandardized fruit and vegetable products (skins of citrus fruits destined for jam, marmalade and candied fruit production, and vegetable stock for use in soups). In addition, pectinase from sources other than *A. niger* is permitted for use in Canada as a food enzyme in all unstandardized fruit and vegetable products. However, pectinase from *A. niger* is not permitted more broadly in this manner in all unstandardized fruit and vegetable products.

The results of the Food Directorate's evaluation of available scientific data support the safety of pectinase from *A. niger* for its requested use. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of pectinase from *A. niger* by adding the new entry subitem (8), shown below, to the List. The food category "unstandardized fruit and vegetable products" includes "skins of citrus fruits destined for jam, marmalade and candied fruit production" [subitem (5)] as well as "vegetable stock for use in soups" [subitem (6)]. Therefore, subitems (5) and (6) in columns 3 and 4 for item P.3 of the List were removed as 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.3	Pectinase	<i>Aspergillus niger</i> var.	(5) [Removed, 2021-01-05, (See NOM/ADM-0157)]	
			(6) [Removed, 2021-01-05, (See NOM/ADM-0157)]	
		
			(8) Unstandardized fruit and vegetable products	(8) Good Manufacturing Practice

Consequential Modification

The previous list entry¹ for pectinase from *A. niger* var. was grouped with another permitted source of pectinase, *Rhizopus oryzae* var. In order to extend the use of pectinase from *A. niger* var. to unstandardized fruit and vegetable products, as indicated in the table above, without modifying the permitted uses of pectinase from *R. oryzae* var., a separate entry for pectinase from *R. oryzae* var. has been added to Item P.3 in the *List of Permitted Food Enzymes*.

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of pectinase from *A. niger* for use as a food enzyme in unstandardized fruit and vegetable products. The assessment concluded that information related to allergenicity, chemistry, microbiology, nutrition and toxicology supports the safety of pectinase from *A. niger* for its requested use. Therefore, the Department has enabled the requested use of pectinase from *A. niger* by modifying the [List of Permitted Food Enzymes](#) as shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as pectinase 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 **January 05, 2021**, 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 pectinase from *A. niger*. 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

¹ The one that appeared in the *List of Permitted Food Enzymes* immediately before the day on which the modification for pectinase from *A. niger*, which is the subject of the present NOM, was made.

electronically. If you wish to contact the Food Directorate electronically, please use the words "**Pectinase (NOM-0157)**" in the subject line of your e-mail.

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