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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Pectinase from *Trichoderma reesei* RF6197 and from *Trichoderma reesei* RF6201 in Single-strength Fruit Juices, Wine and Unstandardized Fruit and Vegetable Products

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: NOM/ADM-0109

February 1, 2018

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

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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 received two food additive submissions seeking approval for the use of polygalacturonase from *Trichoderma reesei* RF6197 and pectin esterase from *Trichoderma reesei* RF6201, respectively, in the manufacture of single-strength fruit juices, wine, fruit purées, vegetable purées, and fruit spreads. The requested maximum level of use for each enzyme is Good Manufacturing Practice (GMP).

Polygalacturonase and pectin esterase are types of pectinase.^{1,2} Pectinase from several microbial sources is already permitted for use as a food enzyme in the manufacture of wine and single-strength fruit juices. Pectinase from one of these source organisms is also permitted broadly in unstandardized fruit and vegetable products, a food category that includes fruit purées, vegetable purées and unstandardized fruit spreads.

Health Canada determined that information related to the safety of pectinase from *Trichoderma reesei* RF6197 and from *Trichoderma reesei* RF6201 supports their use in the manufacture of single-strength fruit juices, wine and unstandardized fruit and vegetable products. Therefore, Health Canada has enabled their use by modifying the [List of Permitted Food Enzymes](#) to include the entries 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>Trichoderma reesei</i> RF6197; <i>Trichoderma reesei</i> RF6201	(1) Single-strength fruit juices	(1) Good Manufacturing Practice
			(2) Unstandardized fruit and	(2) Good Manufacturing Practice

¹ Garg, G. *et al.* "Microbial Pectinases: An Ecofriendly Tool of Nature for Industries." 3 Biotech 6.1 (2016): 47. [<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4746199/>]

² Chapter 11 of "Enzymes in Food Technology", edited by Robert J. Whitehurst and Maarten van Oort, second edition, 2010.

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Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
			vegetable products	
			(3) Wine	(3) Good Manufacturing Practice

Corrective Modification

To maintain the convention in the English version of the Lists of Permitted Food Additives of listing food additives in alphabetical order, the entry for phospholipase in the [List of Permitted Food Enzymes](#) has been moved to a new item number, P.5.2., and item number P.5A has been removed from the List. Phospholipase now appears after peroxidase (item no. P.5.1) and before protease (item no. P.6). This corrective modification has no impact on the permitted food uses of phospholipase or any other permitted food enzyme.

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of the requested uses of pectinase (as polygalacturonase) from *Trichoderma reesei* RF6197 and pectinase (as pectin esterase) from *Trichoderma reesei* RF6201. The assessment did not identify any chemical, microbiological, molecular biological, nutritional or toxicological concerns. Therefore, the Department has enabled the requested uses of these two pectinases 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 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* contain specifications prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and are published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force **February 1, 2018**, the day it was published in the [List of Permitted Food Enzymes](#).

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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 *Trichoderma reesei* RF6197 or from *Trichoderma reesei* RF6201. Anyone wishing to submit new scientific information on the use of these additives 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 "**pectinase (NOM/ADM-0109)**" in the subject line of your e-mail.

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