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# Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Lipase from *Trichoderma reesei* RF10625 in Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0123]

September 6, 2018

Bureau of Chemical Safety  
Food Directorate  
Health Products and Food Branch



Canada

## Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Lipase from *Trichoderma reesei* RF10625 in Bread, Flour, Whole Wheat Flour and Unstandardized Bakery

### 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 lipase from *Trichoderma reesei* RF10625 in bread, flour, whole wheat flour and unstandardized bakery products. The enzyme is intended to be used at a level consistent with Good Manufacturing Practice (GMP).

Lipase from other source organisms is already permitted for use in Canada as a food enzyme in bread, flour, whole wheat flour and unstandardized bakery products.

The Food Directorate concluded that information related to the safety of lipase from *T. reesei* RF10625 supports enabling its use in the foods of interest. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to enable the requested uses of lipase from this source by adding to the list the entries shown in columns 2, 3 and 4 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
L.2	Lipase	<i>Trichoderma reesei</i> RF10625	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
			(2) Unstandardized bakery products	(2) Good Manufacturing Practice

### Rationale

The Food Directorate completed a premarket safety assessment of the requested uses of lipase from *Trichoderma reesei* RF10625. The assessment concluded that information related to chemistry, microbiology, molecular biology, nutrition, and toxicology support the safety of

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lipase from this source for its requested uses. Therefore, Health Canada has enabled the requested uses of lipase from *T. reesei* RF10625 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 lipase 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* are both 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 **September 6, 2018**, 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 lipase from *Trichoderma reesei* RF10625. 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 "**Lipase (NOM-0123)**" in the subject line of your e-mail.

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