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Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Lipase from *Candida cylindracea* AE-LAYH in Bread, Flour, Whole Wheat Flour, Unstandardized Bakery Products, Dairy-based Flavouring Preparations and Modified Fats and Oils

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0100]

August 18, 2017

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 Health Canada’s 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 a food additive submission seeking approval for the use of lipase from the yeast *Candida cylindracea* AE-LAYH at a maximum level of use consistent with Good Manufacturing Practice (GMP) in bread, flour, whole wheat flour, unstandardized bakery products, dairy-based flavouring preparations and modified fats and oils. This enzyme is intended to function as a dough conditioner in bakery applications; to help in the development of flavour in enzyme-modified cheese paste and enzyme-modified dairy paste which are in turn used to flavour certain foods; and it would also be used in the manufacture of modified fats and oils, in particular, docosahexaenoic acid (DHA)-eicosapentaenoic acid (EPA) fish oil concentrates.

The [List of Permitted Food Enzymes](#) already permits the use of lipase from other source organisms in the manufacture of the foods of interest to the petitioner. Lipase from *Candida rugosa* in particular is permitted in “dairy-based flavouring preparations”, a food category that includes enzyme-modified cheese paste and enzyme-modified dairy paste.

The results of Health Canada’s evaluation of available scientific data support the safety of lipase from *C. cylindracea* AE-LAYH for use as requested by the petitioner. Therefore, Health Canada has enabled the requested uses of lipase from *C. cylindracea* AE-LAYH by adding the entries shown below to Columns 2, 3 and 4 of item L.2 in the *List of Permitted Food Enzymes*.

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>Candida cylindracea</i> AE-LAYH	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
			(2) Dairy-based flavouring preparations	(2) Good Manufacturing Practice

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			(3) Modified fats and oils	(3) Good Manufacturing Practice
			(4) Unstandardized bakery products	(4) Good Manufacturing Practice

A corrective modification has also been made to address a duplicative entry for the use of lipase from “*Mucor circinelloides* f. *circinelloides* (previous name: *Mucor javanicus*)” in “Dairy-based flavouring preparations”.

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of the requested uses of lipase from the yeast *Candida cylindracea* AE-LAYH. The assessment did not identify any microbiological, toxicological, chemical or nutritional concerns with these uses of this enzyme from this source organism. Therefore, Health Canada has enabled the use of lipase from *C. cylindracea* AE-LAYH 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 from *C. cylindracea* AE-LAYH 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*, which contains specifications prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and includes JECFA’s *General Specifications and Considerations for Enzyme Preparations*, is published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force on August 18, 2017, 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

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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 *C. cylindracea* AE-LAYH. 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 word "**lipase**" in the subject line of your e-mail.

[Bureau of Chemical Safety, Food Directorate](#)

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