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# Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Milk Coagulating Enzyme from *Rhizomucor miehei* CBS 146319 in Yogurt

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0173

September 17, 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 milk coagulating enzyme from *Rhizomucor miehei* CBS 146319 in the manufacture of yogurt at a maximum level consistent with Good Manufacturing Practice (GMP).<sup>1</sup>

Milk coagulating enzyme from wild-type *R. miehei* (Cooney and Emerson) is already permitted for use in Canada in the manufacture of various standardized cheeses, sour cream, dairy-based flavouring preparations, and hydrolyzed animal, milk and vegetable protein. Milk coagulating enzyme from other microbial sources is already permitted in some of these foods. However, milk coagulating enzyme from any source has not been permitted in the manufacture of yogurt.

The results of the Food Directorate's evaluation of available scientific data support the safety of milk coagulating enzyme from *R. miehei* CBS 146319 for its requested use. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to enable the use of milk coagulating enzyme from *R. miehei* CBS 146319 in the manufacture of yogurt by adding the entry shown below to 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
M.1	Milk coagulating enzyme	<i>Rhizomucor miehei</i> CBS 146319	Yogurt	Good Manufacturing Practice

## Rationale

Health Canada's Food Directorate completed a premarket safety assessment of milk coagulating enzyme from *R. miehei* CBS 146319 for use as a food enzyme in the manufacture of yogurt. The Department concluded that information related to allergenicity, chemistry, microbiology, molecular biology, nutrition, and toxicology supports the safety of milk coagulating enzyme from *R. miehei* CBS 146319 for its requested

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<sup>1</sup> See the definition of Good Manufacturing Practice in the [Marketing Authorization for Food Additives That May Be Used as Food Enzymes](#).

use. Therefore, the Department has enabled the requested use of milk coagulating enzyme from *R. miehei* CBS 146319 by adding to the [List of Permitted Food Enzymes](#) the new entry shown in the above table.

## Other Relevant Information

The *Food and Drug Regulations* require that food additives such as milk coagulating enzyme 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 Specifications in 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), both of which are published by the Food and Agriculture Organization of the United Nations.

## Implementation and Enforcement

The above modification came into force **September 17, 2021**, the day it was published in [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 new scientific information on the safety in use of any permitted food additive, including milk coagulating enzyme from *R. miehei* CBS 146319. Anyone wishing to submit new scientific information on the use of this additive or to submit inquiries on this modification may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**milk coagulating enzyme (NOM-0173)**" in the subject line of your e-mail.

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