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# Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Chymosin B from *Kluyveromyces lactis* CIN in Certain Dairy Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0091]

April 19, 2017

Bureau of Chemical Safety  
Food Directorate  
Health Products and Food Branch



Canada

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from *Kluyveromyces lactis* CIN in Certain Dairy Foods**

## Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug 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 chymosin B from the yeast *Kluyveromyces lactis* CIN in dairy products such as cheese, quark (a type of fresh cheese), and fermented milk products such as yogurt, kefir and sour cream. This enzyme hydrolyses a protein in milk, which causes the milk to clot. Clotting of milk is essential in the manufacture of some dairy products, including those of interest to the petitioner.

Chymosin B from other source organisms, including *Kluyveromyces marxianus* var. *lactis* (DS1182) (pKS105), is already permitted for use in Canada as a food enzyme in the manufacture of various dairy products. However, *K. lactis* CIN has not previously been permitted as a source organism for any enzyme on the *List of Permitted Food Enzymes*.

The results of Health Canada's evaluation of available scientific data support the safety of chymosin B from *K. lactis* CIN for use as requested by the petitioner. Therefore, to enable the requested use of this enzyme from this source organism, Health Canada has modified the [List of Permitted Food Enzymes](#) by adding the entry shown in the table 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
C.3	(ii) Chymosin B	<i>Kluyveromyces lactis</i> CIN	(1) Cheddar cheese; (naming the variety) Cheese; Cottage cheese; Cream cheese; Cream cheese with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Sour cream	(1) Good Manufacturing Practice

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			(2) Unstandardized milk-based dessert preparations	(2) Good Manufacturing Practice
			(3) Kefir; Quark; Yogurt	(3) Good Manufacturing Practice

## Rationale

Health Canada's Food Directorate completed a premarket safety assessment of the requested uses of chymosin B obtained from *K. lactis* CIN. The assessment did not identify any toxicological, nutritional, microbiological, molecular biological or chemical food safety concerns with respect to the requested uses of chymosin B from this source organism. Therefore, Health Canada has enabled the requested uses of this enzyme from this source 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 chymosin B from *K. lactis* CIN 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 includes the *General Specifications and Considerations for Enzyme Preparations*, is 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 **April 19, 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

Health Canada's Food Directorate is committed to reviewing any new scientific information on the safety in use of any food additive, including chymosin B from *K. lactis* CIN. Anyone wishing to submit new scientific information on the use of this food additive or to submit any inquiries

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may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**chymosin B**" in the subject line of your e-mail.

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