

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 chymosin from *Aspergillus niger* DSM 32805 in cheese and fermented milk production at a level consistent with Good Manufacturing Practice. The food enzyme is intended to be used in the production of 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, unstandardized milk-based dessert preparations (e.g. custards, puddings, frozen yogurt, and flan), kefir, quark, and yogurt.

Chymosin and chymosin A from other sources are already permitted for use in the foods requested by the petitioner, except for kefir, quark, and yogurt. Chymosin B from *Kluyveromyces lactis* CIN is already permitted for use in all of the foods requested by the petitioner. However, *A. niger* DSM 32805 is not a permitted source for any food enzyme in Canada.

The results of the Food Directorate's evaluation of available scientific data support the safety of chymosin from *A. niger* DSM 32805 when used as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to enable the use of chymosin from *A. niger* DSM 32805 by adding the new entries 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 |
|----------|-------------------|---------------------------------------|--|--|
| C.3 | (iii) Chymosin | <i>Aspergillus niger</i> DSM 32805 | (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 |
| | | | (2) Kefir; Quark; Yogurt | (2) Good Manufacturing Practice |
| | | | (3) Unstandardized milk-based dessert preparations | (3) Good Manufacturing Practice |

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of chymosin from *A. niger* DSM 32805 for use as a food enzyme in certain milk- and dairy-based foods. The assessment concluded that information related to allergenicity, chemistry, microbiology and molecular biology, nutrition, and toxicology supports the safety of chymosin from *A. niger* DSM 32805 for its requested uses. Therefore, the Department has enabled the requested use of chymosin from *A. niger* DSM 32805 by adding to the [List of Permitted Food Enzymes](#) the new entries shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as chymosin 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 *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) and published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force **April 26, 2021**, 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 new scientific information on the safety in use of any food additive, including chymosin from *A. niger* DSM 32805. Anyone wishing to submit new scientific information on the use of this additive or to submit inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**Chymosin (NOM-0165)**" in the subject line of your e-mail.

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