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Health Canada's Proposal to Enable the Use of the New Food Additive, Cyprosin from the Flower of *Cynara cardunculus* L. var. *atilis* DC., as a Food Enzyme in Various Standardized Cheeses

Notice of Proposal – *Lists of Permitted Food Additives*

December 01, 2014

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

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 the milk clotting (coagulating) enzyme cyprosin, obtained from the flower of the cardoon plant (*Cynara cardunculus* L. var. *altilis* DC.), in cheese making. The enzyme is proposed for use at a maximum level consistent with good manufacturing practice. The cheeses of interest are subject to the compositional standards set out in the *Food and Drug Regulations* for: Cream Cheese, Cream Cheese with (naming the added ingredients), Cottage Cheese and (Naming the variety) Cheese.

The results of Health Canada's evaluation of available scientific data support the safety of cyprosin from this plant source when used in cheese making. Therefore, it is the intention of Health Canada to modify the [List of Permitted Food Enzymes](#) by adding the following entry to the list.

Proposed Modification to the *List of Permitted Food Enzymes*

Item No.	Additive	Permitted Source	Permitted in or upon	Maximum Level of Use and Other Conditions
C.4	Cyprosin	<i>Cynara cardunculus</i> L. var. <i>altilis</i> DC.	Cream cheese; Cream cheese with (naming the added ingredients); Cottage cheese; (Naming the variety) cheese	Good Manufacturing Practice

Rationale

Health Canada's Food Directorate has completed a pre-market safety assessment of the use of cyprosin obtained from *Cynara cardunculus* L. var. *altilis* DC. in cheese making. The assessment considered microbiological, chemical, toxicological, and allergenic aspects of this

enzyme when used as described in the table above. No safety concerns were identified by this assessment.

Cynara cardunculus, or cardoon, has been traditionally cultivated as a vegetable for human consumption and its flowers have a history of use in some areas of Spain and Portugal as a rennet substitute in making traditional sheep cheese.¹

The long history of use of cardoon flower extracts, and the absence of reports of toxicity from such use, support that cyprosin, obtained by extraction from the flowers of *Cynara cardunculus* L. var. *altilis* DC., is safe for use as a food enzyme in the manufacture of cheese.

Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of cyprosin obtained from *Cynara cardunculus* L. var. *altilis* DC. when used under the conditions of use set out in the table above. The Department is therefore proposing to enable the use of cyprosin from this source as described in that table.

Other Relevant Information

The Codex General Standard for Food Additives (GSFA) contains few provisions for food enzymes and none for cyprosin. However, the Codex General Standard for Cheese (CODEX STAN 283-1978) provides for rennet or other suitable coagulating agents to be used in making cheese. In addition, the Codex Standard for Cream Cheese (CODEX STAN 275-1973) and the Codex Standard for Cottage Cheese (CODEX STAN 273-1968) permit the use of rennet or other safe and suitable coagulating enzymes as ingredients in cheeses subject to these standards.

In Australia and New Zealand, the standard for cheese (Standard 2.5.4) permits rennet or other suitable coagulating agents to be used in making cheese. Food enzymes require pre-market approval as processing aids in Australia and New Zealand, and cyprosin is not identified as a permitted processing aid.

In Europe, the use of food enzymes is subject to national legislation. Cyprosin is permitted for use in Portugal, Spain, France and the Netherlands.

In the United States of America, there are standards² for individual cheeses that, in Canada, are subject to the standard for (Naming the variety) cheese. A number of these standards in the United States permit the cheeses to be made with rennet and/or other clotting enzymes of animal, plant, or microbial origin. Cream cheese can be manufactured with these enzymes, as can cream cheese with other foods since the latter is made with cream cheese. Rennet and/or other safe and suitable clotting enzymes are permitted for use in making dry curd cottage cheese, which in turn is used to make cottage cheese.

¹ Fernández J. et al. 2006. Industrial applications of *Cynara cardunculus* L. for energy and other uses. *Industrial Crops and Products* 24:222-229

² The standards are in Title 21 of the Code of Federal Regulations, Part 133 (21 CFR 133).

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Health Canada and the Canadian Food Inspection Agency (CFIA) jointly administer Canada's food compositional standards, including the standards for the cheeses that could be manufactured with cyprosin. Health Canada consulted the CFIA and two associations that represent the dairy industry about the proposed use of cyprosin. None of these organizations objected to the use of this enzyme in cheese making.

The *Food and Drug Regulations* require that all food enzymes used as food additives meet the specifications for enzyme preparations set out in the most recent edition of the *Food Chemicals Codex* (FCC). The FCC is a compendium of standards for purity and identity of food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

Cyprosin, as with other additives used in cheese making, would be required to be declared in the list of ingredients on the label of prepackaged cheeses that have been manufactured with this enzyme.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the [List of Permitted Food Enzymes](#). This will be announced via a Notice of Modification which will be published on the [Food and Nutrition - Public Involvement and Partnerships](#) section of Health Canada's Website.

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

For additional information or to submit comments related to this proposal, please contact:

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

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If communicating by e-mail, please use the word "**cyprosin**" in the subject line of your e-mail. Health Canada is able to consider information received by **February 13, 2015**, 75 days from the date of this posting.