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# Health Canada's Proposal to Enable the Use of Carboxypeptidase Obtained from *Aspergillus niger* PEG-1 as a Food Enzyme in Dairy-based Flavouring Preparations, Mascarpone, and Certain Standardized Cheeses and Meats

Notice of Proposal – *Lists of Permitted Food Additives*

March 4, 2015

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 food enzyme carboxypeptidase obtained from *Aspergillus niger* PEG-1 in cheddar cheese, various cheeses that meet the standard for "(naming the variety) Cheese", mascarpone, enzyme modified cheese, aged cured ham, dried cured sausage, sausage meat mix, pepperoni, prosciutto, salami and summer sausage. Enzyme modified cheese is used as an ingredient to impart cheese flavour to other foods and is considered a dairy-based flavouring preparation.

Carboxypeptidase can be used to accelerate the development of flavour in cheese and fermented meat. It can also function by having a debittering effect during the manufacture of cheese and enzyme modified cheese.

The results of Health Canada's evaluation of available scientific data support the safety of carboxypeptidase obtained from *Aspergillus niger* PEG-1 when used as requested by the petitioner. Therefore, Health Canada intends to modify the [List of Permitted Food Enzymes](#) by adding the following entry to the list which will accommodate the food uses of carboxypeptidase requested by the petitioner.

### Text of Proposed 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.01	Carboxypeptidase	<i>Aspergillus niger</i> PEG-1	Cheddar cheese; Dairy based flavouring preparations; Mascarpone; (naming the variety) Cheese; Preserved meat (Division 14); Sausage	Good Manufacturing Practice

## Rationale

Health Canada's Food Directorate has completed a pre-market safety assessment of carboxypeptidase from *Aspergillus niger* PEG-1 when used as requested by the petitioner. The assessment considered microbiological, chemical, toxicological, nutritional and allergenic aspects of the proposal.

Carboxypeptidase is a protease enzyme. Proteases, including some derived from *Aspergillus niger*, have been previously approved as food additives in Canada for a variety of uses. The production organism, *Aspergillus niger*, has a long history of use as a source of enzymes used in the food industry. It is widely distributed in nature and consequently is a normal constituent of the diet. It is recognized as a non-pathogenic and non-toxicogenic organism.

Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of carboxypeptidase from the strain of *Aspergillus niger* known as PEG-1 when the enzyme is used under the conditions set out in the table above. The Department is therefore proposing to enable the use of carboxypeptidase from this source as described above.

## Other Relevant Information

There is an entry for serine-type carboxypeptidase from *Aspergillus niger* in the *Inventory of Substances Used as Processing Aids (IPA), Updated List*<sup>1</sup>. The inventory is a document maintained by the Codex Committee on Food Additives, a committee of the Codex Alimentarius Commission. Serine-type carboxypeptidase is the type of carboxypeptidase that was the subject of the present food additive submission filed with Health Canada.

In the United States of America, a Generally Recognized as Safe (GRAS) notice (GRN 000345) for carboxypeptidase enzyme preparation from *Aspergillus niger* PEG-51A, which is of the same strain lineage as the PEG-1 strain, was submitted to the Food and Drug Administration (FDA) for review. In response, the FDA indicated that the Agency had no questions at that time regarding the petitioner's determination that the carboxypeptidase enzyme preparation is GRAS under the intended conditions of use in the production of cheese, enzyme-modified cheese, and fermented meat.<sup>2</sup>

In Australia and New Zealand, food enzymes are regulated as processing aids under Standard 1.3.3 of the *Australia New Zealand Food Standards Code*. Carboxypeptidase is not listed in the table of processing aids that are permitted for use as enzymes.

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<sup>1</sup> FA/45 INF/03 (February 2013). Available at: [ftp://ftp.fao.org/codex/meetings/ccfa/ccfa45/fa45\\_inf3x.pdf](ftp://ftp.fao.org/codex/meetings/ccfa/ccfa45/fa45_inf3x.pdf)

<sup>2</sup> Letter of December 22, 2010, from M. Cheeseman to G. Yingling Re. GRAS Notice No. GRN 000345. Available at: <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm240070.htm>

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The use of food enzymes is subject to national legislation in Europe. In France, the Agence française de sécurité sanitaire des aliments gave a favourable opinion for the use of carboxypeptidase enzyme preparation obtained from *Aspergillus niger* PEG-1 to be used in the production of certain cheeses, “cheese” flavours, and products based on fermented meat.<sup>3</sup>

Health Canada and the Canadian Food Inspection Agency (CFIA) jointly administer Canada's food compositional standards, including any standards for cheeses and meat products that could be manufactured with carboxypeptidase. Health Canada consulted the CFIA and four associations that represent the dairy and meat industries about the proposed use of carboxypeptidase. No technical or safety-based rationale opposing the proposed use of carboxypeptidase from *Aspergillus niger* PEG-1 was filed in response to this consultation.

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.

### 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:

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If communicating by e-mail, please use the word “**carboxypeptidase**” in the subject line of your e-mail. Health Canada is able to consider information received by **May 17, 2015**, 75 days from the date of this posting.

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<sup>3</sup> Opinion of the Agence française de sécurité sanitaire des aliments regarding the application for authorization of the use of a serine type carboxypeptidase produced from a genetically modified strain of *Aspergillus niger* intended for the dairy industry (cheese, “cheese” flavors) and the manufacture of products based on fermented meat. December 22, 2008.