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Health Canada's Proposal to Enable the Use of a New Food Additive, *Carnobacterium divergens* M35, as an Antimicrobial Preservative in Sliced Ready-to-Eat Cold-Smoked Salmon and Sliced Ready-to-Eat Cold-Smoked Trout

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0018]

June 07, 2016

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 a live culture preparation of the bacterium *Carnobacterium divergens* M35 to limit or inhibit the growth of the foodborne pathogen *Listeria monocytogenes* on sliced ready-to-eat cold-smoked salmon and sliced ready-to-eat cold-smoked trout.

Marine food products in general can be susceptible to the growth of several pathogens, and fish can provide an environment for the growth of the pathogen *L. monocytogenes*. This bacterium is capable of surviving the cold-smoking process that is used to make ready-to-eat cold-smoked fish products and it can grow at refrigeration temperatures. As a result, sliced ready-to-eat cold-smoked salmon and trout, which are sold refrigerated, are food products that could potentially harbour *L. monocytogenes*.

Certain bacteria produce antimicrobial peptides (proteins) known as bacteriocins. *Carnobacterium divergens* M35 produces divergicin M35, which is a bacteriocin to which *L. monocytogenes* is susceptible.

The *C. divergens* M35 product that is proposed for use on sliced ready-to-eat cold-smoked salmon and trout is a suspension, in water, of live *C. divergens* M35 cells and the fermentation medium containing divergicin M35. The petitioner who filed the food additive submission indicated that in order for it to be effective as an antimicrobial treatment, the culture of *C. divergens* M35 must be applied to the sliced ready-to-eat cold-smoked salmon or trout and allowed to grow and produce its bacteriocin *in situ*. The aqueous suspension can be sprayed onto cold-smoked salmon or trout by the cold-smoked fish manufacturer prior to packaging of the sliced products.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of *C. divergens* M35 when used as requested by the petitioner. Therefore, it is the intention of Health Canada to modify the *List of Permitted Preservatives* by adding the following entry to the list:

Proposed Modification to Part 2 of the *List of Permitted Preservatives*

Item No.	Column 1 Additive	Column 2 Permitted in or upon	Column 3 Maximum Level of Use and Other Conditions
C.1A	*Carnobacterium divergens* M35	Sliced ready-to-eat cold-smoked salmon; Sliced ready-to-eat cold-smoked trout	Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of the bacterium *C. divergens* M35. The assessment considered microbiological, toxicological, chemical and technical aspects relevant to *C. divergens* M35 when used as described above.

C. divergens M35 is a lactic acid bacterium. Lactic acid bacteria have a long history of food use and they do not pose a health risk to the general population. *Carnobacterium divergens* species are found naturally in the environment and have been isolated from dairy, meat, and fish products. *Carnobacterium divergens* M35 was isolated from mussels.

Bacteriocins produced by lactic acid bacteria are likely already consumed as part of a normal diet. Since they are easily broken down by proteolytic enzymes in the human gastrointestinal tract, and the resulting single amino acids would be normal dietary constituents, they do not pose a food safety concern.

Carnobacterium species are known to produce biogenic amines. From a food safety perspective, histamine and tyramine are probably the two most important biogenic amines of bacterial origin in food. The potential production of biogenic amines by *C. divergens* M35 when used as a food additive was assessed. Only tyramine showed a potential to increase over time. However, the levels of tyramine observed over the shelf-life of fish products treated with *C. divergens* M35 were well below levels found in many commonly consumed foods, such as cheddar cheese, beer, and aged chicken livers.

The food additive submission included efficacy data demonstrating that sliced ready-to-eat cold-smoked salmon treated with a *C. divergens* M35 preparation did not support the growth of *L. monocytogenes* during the food product's intended shelf-life, whereas growth of this pathogen increased during the shelf-life of untreated controls. The efficacy data provided were judged acceptable for sliced ready-to-eat cold smoked trout as well.

Based on the results of the premarket evaluation, Health Canada's Food Directorate considers that the data support the safety and efficacy of *C. divergens* M35 when used under the conditions

set out in the table above. The Department is therefore proposing to enable the use of *C. divergens* M35 as described in the above table.

Other Relevant Information

As of the time the food additive submission was filed in Canada, the petitioner had not filed any requests with other jurisdictions for the same use of *C. divergens* M35.

The Canadian *Food and Drug Regulations* require that food additives meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC) if there are no specifications in the Regulations. The FCC is a compendium of standards for purity and identity for food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

The FCC contains an appendix with information about food uses of live microbial cultures, but there are no monographs with requirements for these cultures. However, the petitioner provided specifications used to control the purity of the *C. divergens* M35 preparation and Health Canada found these specifications to be acceptable from a microbiological perspective.

Implementation and Enforcement

The proposed change will be effective the day on which it is published in the *List of Permitted Preservatives*. This will be announced via a Notice of Modification which will be published on 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 words "***Carnobacterium divergens* M35**" in the subject line of your e-mail. Health Canada is able to consider information received by **August 20, 2016**, 75 days from the date of this posting.