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# Notice of Modification to the *List of Permitted Preservatives* to Enable the Use of *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 Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0079]

October 13, 2016

Bureau of Chemical Safety  
Food Directorate  
Health Products and Food Branch



Canada

Notice of Modification to the *List of Permitted Preservatives* to Enable the Use of *Carnobacterium divergens* M35 as an Antimicrobial Preservative in Sliced Ready-to-Eat Cold-Smoked Salmon and Sliced Ready-to-Eat Cold-Smoked Trout  
- Reference Number: [NOM/ADM-0079]

## 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.

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. Since this is a food additive that was not previously permitted for use in Canada, Health Canada published a notice of the Department's proposal to enable the use of this antimicrobial preservative, titled [Notice of 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 - Reference Number: NOP/AVP-0018](#).

The proposal was published on June 7, 2016, and was open for public comment for 75 days. Health Canada received one comment in response to the proposal (see below), but no new scientific information was submitted that changed the outcome of the safety evaluation. Since the conclusion of the evaluation remains as described in the proposal, Health Canada has modified the [List of Permitted Preservatives](#) as indicated below.

### Modifications 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	<i>Carnobacterium divergens</i> M35	Sliced ready-to-eat cold-smoked salmon; Sliced ready-to-eat cold-smoked trout	Good Manufacturing Practice

## Rationale

Health Canada's Food Directorate assessed the safety and efficacy of *C. divergens* M35 for its proposed use as an antimicrobial preservative 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. The assessment focused on toxicological and microbiological aspects related to the proposed use of the live bacterial culture of this microorganism.

Overall, the data that were assessed support the safety and efficacy of *C. divergens* M35 when used under the conditions of use set out in the table above. Therefore, Health Canada has enabled the requested use of *Carnobacterium divergens* M35 by modifying the [\*List of Permitted Preservatives\*](#) as described in the above table.

## Notification – Summary of Comments

One comment was submitted to Health Canada in response to the [\*Notice of 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 - Reference Number: NOP/AVP-0018\*](#). The comment expressed concerns about the potential health impact of the proposed use of *C. divergens* M35 for individuals with weakened immune systems citing a case report in the scientific literature.

Health Canada reviewed the case report, which was about a hospitalised individual with multiple health concerns who also had an infection with *C. divergens*. The route of exposure was not confirmed but was presumed to be contamination of a solution in a feeding tube or colonization of the feeding tube itself. Other studies cited in the case report were also considered. These described the isolation of *Carnobacterium* species either in human blood or exudate. The individuals were thought to have been exposed to naturally-occurring bacteria, including *Carnobacterium* species, not from the consumption of food but rather through skin lesions or traumatic wounds. The reports were not considered to present any information that would indicate that the use of *C. divergens* M35 on cold-smoked fish poses a health risk for the general population.

It is recognised that persons with weakened immune systems are more vulnerable to pathogenic microorganisms than the general population. This is reflected in advice that Health Canada has already issued on food safety for persons with weakened immune systems, who may be more vulnerable to food poisoning than others.<sup>1</sup> One of Health Canada's recommendations is that persons with this condition not consume certain foods, including refrigerated, smoked seafood. This advice is based on the potential for exposure to pathogenic microorganisms, such as *Listeria*

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<sup>1</sup> [Food safety for people with a weakened immune system](http://healthycanadians.gc.ca/eating-nutrition/healthy-eating-saine-alimentation/safety-salubrite/vulnerable-populations/immune-immunitaire-eng.php?_ga=1.266830536.778844979.1465568688) : ([http://healthycanadians.gc.ca/eating-nutrition/healthy-eating-saine-alimentation/safety-salubrite/vulnerable-populations/immune-immunitaire-eng.php?\\_ga=1.266830536.778844979.1465568688](http://healthycanadians.gc.ca/eating-nutrition/healthy-eating-saine-alimentation/safety-salubrite/vulnerable-populations/immune-immunitaire-eng.php?_ga=1.266830536.778844979.1465568688))

*monocytogenes*, as opposed to such microorganisms as *C. divergens* M35 which is recognised as non-pathogenic.

The use of *C. divergens* M35 will be another option for manufacturers of sliced ready-to-eat cold-smoked salmon and sliced ready-to-eat cold-smoked trout to implement in order to reduce contamination of these foods by the pathogen *Listeria monocytogenes*. Overall, the available scientific data supports enabling the use of *C. divergens* M35 as Health Canada proposed.

## Implementation and Enforcement

The above modification came into force **October 13, 2016**, the day it was published in the [\*List of Permitted Preservatives\*](#).

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 ***Carnobacterium divergens* M35**. Anyone wishing to submit new scientific information on the use of this additive or to submit any inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "***Carnobacterium divergens* M35**" in the subject line of your e-mail.

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

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