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Health Canada's Proposal to Enable the Use of *Leuconostoc carnosum* 4010 as an Antimicrobial Preservative in Certain Vacuum-Packed Non-Shelf-Stable Meat and Poultry Products

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0016]

April 12, 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 the bacterium *Leuconostoc carnosum* 4010 as an antimicrobial preservative at a maximum level of use consistent with Good Manufacturing Practice in certain vacuum-packed non-shelf-stable meat and poultry products, namely: bologna, cervelat, frankfurters, mortadella, and wieners.

The results of Health Canada’s evaluation of available scientific data support the safety and efficacy of *L. carnosum* 4010 when used as described. Therefore, it is the intention of Health Canada to modify Part 2 of 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
L.1	<i>Leuconostoc carnosum</i> 4010	Vacuum-packed bologna; Vacuum-packed cervelat; Vacuum-packed frankfurters; Vacuum-packed mortadella; Vacuum-packed wieners	Good Manufacturing Practice

All of the above-mentioned products, except when made with poultry, are subject to the compositional standard for “Sausage or Sausage Meat” set out in section B.14.032 of the *Food and Drug Regulations*. Although this standard permits lactic acid-producing starter culture in sausage, *Leuconostoc carnosum* 4010, which is a lactic acid producing bacterium, is added to prevent the growth of *Listeria monocytogenes*, not to function as a starter culture. True starter cultures are used to initiate product fermentation and to achieve consistency in fermentation results.

Rationale

Health Canada's Food Directorate has completed its pre-market safety and efficacy assessment of *Leuconostoc carnosum* strain 4010. The assessment considered microbiological and toxicological aspects of *L. carnosum* 4010 when used as described above. It was noted that the application of *L. carnosum* 4010 affects neither the nutritional nor the organoleptic quality of the treated food products.

L. carnosum has been found to occur naturally in wiener sausages and cooked ham, and had historically been associated only with its potential to cause spoilage of vacuum-packed meat. However, research conducted in the late 1990s identified strains of *L. carnosum* that were not associated with spoilage and which produced bacteriocins, which are ribosomally synthesized antimicrobial peptides produced by one bacterium that are specifically active against other bacteria. The bacteriocins produced by *L. carnosum* 4010 (formerly known as *L. carnosum* 1043) are small heat-stable peptides that act against *Listeria monocytogenes* by inhibiting cell wall synthesis or by producing small holes in the cell membrane resulting in the death of this spoilage and pathogenic microorganism.

The *L. carnosum* 4010 culture would be applied as part as of a freeze-dried preparation to emulsion-type meat and poultry products at a rate of 1×10^6 to 1×10^7 colony forming units per gram of the meat/poultry product. The bacterium would remain active throughout the shelf-life of treated sausage products.

No microbiological concerns were identified with respect to the proposed use of *L. carnosum* 4010. Data was provided demonstrating that vacuum-packed cooked emulsion-type sausages (e.g., wiener sausages, and sliced cervelat) treated with a preparation containing *L. carnosum* 4010 would not support the growth of *Listeria monocytogenes* during the sausage's intended shelf-life, whereas growth of *Listeria monocytogenes* increased during the shelf-life of untreated sausages.

Health Canada assessed the toxicological safety of the bacterium itself (*L. carnosum* 4010), the bacteriocins it produces, and the potential for this microorganism to produce biogenic amines. Lactic acid bacteria, including *L. carnosum* 4010, have a long history of use in fermented foods and are commonly present in food and the human digestive tract. In general, they are not considered to pose a health concern to the general population.

While there have been reports in the scientific literature of rare cases of *L. carnosum* strains being opportunistic pathogens, these instances are not relevant to the proposed food additive use of this organism. In the context of its use in food, *L. carnosum* 4010 is not considered a pathogen.

No safety concerns about exposure to bacteriocins were identified from a toxicological perspective. Bacteriocins produced by lactic acid bacteria are likely already consumed as part of a normal diet. Bacteriocins produced by lactic acid bacteria can be considered to be safe biopreservatives as they are easily broken down by proteolytic enzymes in the human gastrointestinal tract and the resulting single amino acids would be normal dietary constituents.

Leuconostoc species are generally known to produce biogenic amines, such as histamine and tyramine. Due to their toxicological effects, histamine and tyramine are probably the two most important biogenic amines of bacterial origin in food. A commercial batch of the live culture *L. carnosum* 4010 was analysed for both of these biogenic amines and neither were found at a level above a limit of detection of 5 mg/L (5 ppm). It was also taken into consideration that *L. carnosum* is commonly found in meat products and it is not expected that this strain (*L. carnosum* 4010) would produce biogenic amines at levels any greater than naturally found on these types of meat products.

Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of *L. carnosum* 4010 when used under the conditions of use set out in the table above. The Department is therefore proposing to enable the use of *L. carnosum* 4010 as described in the above table.

Other Relevant Information

The petitioner indicated that products containing *L. carnosum* 4010 have been successfully introduced to the European meat industry, in particular for processed meat products. Health Canada is not aware of its regulatory status in other jurisdictions.

The Canadian *Food and Drug Regulations* require that food additives such as *L. carnosum* 4010, which do not have specifications set out in the Regulations, meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC). 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 currently there are no monographs with requirements for these cultures. The petitioner did however provide specifications used to control the purity of the commercial product containing *L. carnosum* 4010. These specifications are considered 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:

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

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If communicating by e-mail, please use the words "**Leuconostoc carnosum 4010**" in the subject line of your e-mail. Health Canada is able to consider information received by **June 24, 2016**, 75 days from the date of this posting.