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Information Document on Health Canada's Proposal to Amend the *Food and Drug Regulations* to permit the use of a microbiological preparation of *Carnobacterium maltaromaticum* strain CB1 in certain ready-to-eat meat and poultry products

Bureau of Chemical Safety

Food Directorate
Health Products and Food Branch

A PAHO/WHO Collaborating Center for Food Contamination Monitoring



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The regulation to permit the use of the food additive *Carnobacterium maltaromaticum* CB1 in certain processed meat and poultry meat products came into force on Thursday, November 18, 2010. Specifically, the approval permits the use of this food additive in vacuum-packed wieners, vacuum-packed sliced roast beef, vacuum-packed sliced cooked ham and vacuum-packed sliced cooked turkey, all at a maximum level of use consistent with Good Manufacturing Practice. These amendments to the *Food and Drug Regulations* will be published in Part II of the *Canada Gazette* on December 8, 2010, however, this food additive and the foods listed above containing the food additive may now be sold in Canada.

Purpose

This document provides information on Health Canada's proposal to amend the *Food and Drug Regulations* ("Regulations") to permit the use of a microbiological preparation composed of both viable as well as pasteurized, non-viable cells of *Carnobacterium maltaromaticum* strain CB1 and its metabolites (such as carnobacteriocins) in certain ready-to-eat (RTE) meat/poultry products as an intervention against human pathogenic microorganisms such as *Listeria monocytogenes*.

Background

In Canada, all food additives are regulated under the *Food and Drug Regulations* and are subjected to rigorous controls under the *Food and Drug Act* and the *Food and Drug Regulations*. Before a food additive is permitted for use, a submission must be filed with Health Canada so the Department can conduct a thorough safety evaluation of the proposed use(s) of the additive. Food manufacturers are not permitted to use the additive until it has been approved by Health Canada and the Regulations have been amended to permit its use.

Products used as antimicrobial preservatives in food applications are considered food additives. Permitted food additives are listed in the food additive tables in Division 16 of the Regulations. Table XI, Part II, lists those food additives that may be used in Canada as antibacterial food preservatives.

Health Canada received two food additive submissions seeking the approval of a preparation consisting of *Carnobacterium maltaromaticum* strain CB1 (herein referred to as *C. maltaromaticum* CB1) for use as an antimicrobial treatment on selected ready-to-eat meat and poultry products, namely: sausage wieners (hotdogs); sliced roast beef; sliced cooked ham; and sliced cooked turkey. All affected products would be packaged under vacuum and would require mandatory

ingredient labelling for 'bacterial culture'. *C. maltaromaticum* CB1 used for this purpose meets the regulatory definition of a food additive but is not currently listed in Division 16, part B of the Regulations.

Description of the Food Additive Use

The *Carnobacterium maltaromaticum* strain CB1 is a gram-positive non spore-forming lactic acid bacteria. The preparation contains both viable as well as non-viable, pasteurized lyophilized cells. It also contains *Carnobacterium maltaromaticum* metabolites of which carnobacteriocins exhibit antibacterial

activity. The *C. maltaromaticum* CB1 preparation would be applied with a liquid applicator or sprayed on the surface of the meat/poultry product at a rate of 1×10^4 colony forming units (CFU) per gram of the RTE meat/poultry product. The bacterium remains active throughout the shelf life of the ready-to-eat food product.

Current Situation

Health Canada has received two submissions (from the same petitioner) requesting that the Regulations be amended to permit the addition of a preparation of *C. maltaromaticum* CB1 as an effective antilisterial treatment for (1) wieners and (2) sliced roast beef and sliced cooked ham and turkey. All affected food products would be vacuum-packed.

Health Canada's Food Directorate has completed its safety assessment of *C. maltaromaticum* CB1 when used as described in both submissions and determined that there are no health or safety concerns with the use of this microbial preparation in the requested food products. The Food Directorate has also concluded that the provided microbiological data demonstrates the efficacy of the preparation in slowing the growth of *Listeria monocytogenes*. Therefore, Health Canada is proposing amendments to the Regulations to allow the use of *C. maltaromaticum* CB1 as proposed.

Safety Assessment

Health Canada's Food Directorate scientists conducted a detailed and rigorous evaluation of both submissions that focussed on safety and efficacy. Their evaluation considered both microbiological and toxicological aspects of the proposed use of *C. maltaromaticum* CB1 as a food additive. It was noted that the

application of *C. maltaromaticum* CB1 affects neither the nutritional nor the organoleptic quality of the treated food products.

Toxicological Assessment and Dietary Exposure

The toxicological assessment of the preparation included the evaluation of the pathogenicity and toxicity of the microorganism, the toxicity and potential allergenicity of the bacteriocins (carnobacteriocins) secreted by the organism and the potential for the organism to produce bioactive amines.

Carnobacteriocins, proteinaceous metabolites of *Carnobacterium maltaromaticum*, are active against certain bacterial strains through specific cellular mechanisms. Presented data demonstrated that carnobacteriocins would be unlikely to survive intact in the human gastric environment; they would therefore not affect the normal human gut flora balance and would not trigger allergic or other adverse reactions in the human organism.

The microorganism *Carnobacterium maltaromaticum* is registered in the American Type Culture Collection ATCC with a designation of not being known to cause disease in a general human adult population. The petitioner provided data to demonstrate that there are no reports of human pathogenicity associated with oral consumption of *Carnobacterium maltaromaticum*. The level of added bacterium is comparable with that ingested through its natural occurrence in many foods, for example meat, seafood or dairy. In some countries the bacterium is used for manufacturing of certain sausages.

The petitioner provided literature reports suggesting that *Carnobacterium* spp. produces tyramine, one of the bioactive amines. This substance derives from metabolism of certain amino acids, i.e. tyrosine, and may occur naturally, in substantial amounts, in various fermented and/or aged foods such as cheeses, alcoholic beverages, yeast or meat extracts, smoked meat, fish or poultry. While the tyramine level may increase in the RTE meat and poultry products with added *C. maltaromaticum* CB1, the data provided showed that the highest detected levels of this biogenic amine were still lower than those naturally occurring in many foods of a normal diet, for example certain ripened cheeses, sausages or oily fish. The amount of tyramine in respective portion sizes of the RTE meat/poultry products treated with *C. maltaromaticum* CB1 would therefore be either comparable to or lower than amounts of this amine in foods consumed by the Canadian population.

Tyramine impacts on certain neurotransmitters which, in turn, can result in an increase in blood pressure and cardiac output. For most people, tyramine is efficiently metabolized by an enzyme, monoamine oxidase. On the basis of experimental data provided by the petitioner, it was demonstrated that even a one-time ingestion of a pound of the RTE meat or poultry products with added *C. maltaromaticum* CB1 would correspond to an intake of tyramine in amounts much lower than those reported as inducing even a transient blood pressure change.

Based on this information, Health Canada's Food Directorate scientists have no objections from a toxicological perspective to the use of *C. maltaromaticum* CB1 on RTE meat and poultry products under the conditions of use proposed in each of the submissions.

Microbiological Assessment

Food Directorate scientists have also concluded that adequate data substantiating the identity of CB1 strain of the lactic acid bacterium *Carnobacterium maltaromaticum* (former name *Carnobacterium piscicola*) were provided. The strain is a naturally occurring isolate which was not genetically modified. The Bureau of Microbial Hazards of the Food Directorate has concluded that the preparation of *Carnobacterium maltaromaticum* strain CB1 had an antimicrobial effect against *Listeria monocytogenes* in the RTE products under consideration.

In general, lactic acid bacteria are known producers of bacteriocins, such as carnobacteriocins. These are peptides not structurally related to any clinically important antibiotics. There is a long history of exposure to various bacteriocins from the consumption of meat products, fish, dairy or vegetable foods, due to the usual bacterial flora of those foods. Consumption of the RTE foods with added *C. maltaromaticum* CB1 strain and its metabolites is unlikely to result in any spread of resistance to antibiotics of clinical importance, given these are peptides not structurally related to any clinically important antibiotics. From a microbiological perspective the strain is considered safe for human consumption at exposure levels that might be achieved in wieners, sliced roast beef, sliced cooked ham or turkey. Therefore the use level of *C. maltaromaticum* CB1 consistent with good manufacturing practice will ensure its antimicrobial effect against *Listeria monocytogenes* without any adverse effects to humans.

From the microbiological perspective no objection has been expressed to the use of *C. maltaromaticum* CB1 in vacuum packed and subsequently refrigerated (to 4°C or less) sliced cooked ham, sliced cooked turkey, sliced roast beef and wieners. As per submitted data, the application would be restricted to vacuum packed foods. A separate submission would be required for extension of use of *C.*

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maltaromaticum CB1 in either other modified atmosphere condition packaging or other food products. Efficacy and safety of use of *C. maltaromaticum* CB1 in newly proposed foods would be considered on a case-by-case basis.

Rationale for Action

Based on the evaluation conducted by Health Canada's scientists, the information provided by the petitioner has satisfactorily met the requirements for a food additive submission outlined in Section B.16.002 of the Regulations. *C. maltaromaticum* CB1 will serve functionally as a preservative and should therefore be considered a food additive. Thus, it is proposed that *Carnobacterium maltaromaticum* strain CB1 be listed as class II antibacterial preservative in Table XI, Part II, to section B.16.100, Division 16 (Food Additives), part B of the *Food and Drug Regulations*. Several compositional standards for meat and poultry products (Divisions 14 and 22 of the *Food and Drug Regulations*) would require amendment as well.

International Status

The US authorities have not objected to the company's conclusion that the application of *C. maltaromaticum* CB1 is Generally Recognized as Safe (GRAS) in a variety of foods, including meat and poultry products (two GRAS Notifications have been filed with the Food and Drug Administration, No. 159 in 2007 and No. 305 in 2010). The use of *C. maltaromaticum* CB1 is listed in the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) directive 7120.1, periodically updated ("Safe and suitable ingredients used in the production of meat, poultry, and egg products").

Recommendations

It is recommended that a provision for *Carnobacterium maltaromaticum* strain CB1, its cells and metabolites, including bacteriocins, be permitted for use upon vacuum packed wieners, sliced roast beef, sliced cooked ham and sliced cooked turkey at a level consistent with good manufacturing practice.

The use of *C. maltaromaticum* CB1 on the described ready-to eat meat and poultry products, all of which are standardized foods, would require amendment of the relevant compositional standards for these foods. Table XI, Part II, Division 16 (Food Additives), would be amended to this effect. Because the proposal involves foods that are standardized under the Food and Drug Regulations, the Canadian

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Food Inspection Agency (CFIA) and the Canadian Meat Council (CMC), a national trade association, were consulted. The CFIA raised no concerns with the proposal. The CMC expressed support for the proposed use of *C. maltaromaticum* CB1."

Both Health Canada and the Canadian Food Inspection Agency recommend that "bacterial culture" be an acceptable labelling term with a voluntary option to disclose the full name of *Carnobacterium maltaromaticum* strain CB1. Such a recommendation complies with labelling rules outlined in sections B.01.009 and B.01.010(3)(b) of the *Food and Drug Regulations*.

Comments

Comments on this proposal may be submitted in writing, either electronically or by regular mail. If you are submitting your comments electronically, please use the term "*C. maltaromaticum*" in the subject box of your e-mail. **Comments must be received by 12:00 a.m. EDT, November 10, 2010.**

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Additional Information

For more information on this initiative, please contact the [Chemical Health Hazard Assessment Division](#) at bcsc-bipc@hc-sc.gc.ca.

This document is also available electronically, at:
www.healthcanada.gc.ca/foodadditives.