



Health
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Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Chemical Health Hazard Assessment Division
Bureau of Chemical Safety
1st Floor East, Postal Locator: 2201C
Tunney's Pasture, Building 22
251 Sir Frederick Banting Driveway
Ottawa, ON K1A 0K9

September 3, 2010

Our file : ADDPS09060102

Mr. Dirk de Meester, Director, Business Development
Dr. Steven Hagens, Chief Scientific Officer

EBI Food Safety
Nieuwe Kanaal 7P
6709 PA Wageningen
The Netherlands

Re: Use of the bacteriophage preparation "Listex P100" as an antimicrobial intervention method against *Listeria monocytogenes* in or on variety of meat, poultry, seafood and cheese products

Dear Mr. de Meester and Dr. Hagens:

This letter responds to your request of June 2009 for the use of the preparation of bacteriophage identified as Listex P100 as an antimicrobial intervention method against *Listeria monocytogenes*. Food products to be treated with Listex P100 would be mainly prepared deli meat and poultry products (e.g. wieners, sliced ham), cold-smoked fish, vegetable prepared dishes, soft cheeses and/or other dairy foods.

Health Canada's Food Directorate has reviewed your submitted material and concluded that at the proposed level of use, that is, within the range of 1×10^7 to 1×10^9 phage per gram of treated food, the antilisterial effect has been demonstrated while no adverse consumer health effects would be expected. The Food Directorate has concurred with your rationale to consider the requested application of Listex P100 a processing aid.

It is our understanding that the label of the preparation will provide clear instructions of the conditions of application to its potential users. We would appreciate receiving the proposed label; a copy can also be conveyed for information to the Non-Food Chemicals Program at the Canadian Food Inspection Agency (CFIA), 1400 Merivale Road, Ottawa, Ontario, K1A 0Y9.

This letter of no objection applies only to the preparation Listex that contains the phage P100

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strain. Any change in the composition of phages of the preparation will render this letter void. Should you wish to modify the composition and specifications of the Listex P100 preparation, we would expect a new submission in support of a new request of use.

Yours sincerely,



Mark Feeley,
A/Chief

cc: Barbara Lee, Director, Bureau of Chemical Safety
Jeffrey Farber, Ph.D., Director, Bureau of Microbial Hazards
Gail Daniels, Chief, Dairy Program, CFIA
Terence McRae, Director, Fish Program, CFIA
Dr. Martin Appelt, National Manager, Meat Program, CFIA
Bernard Dallaire, Non-Food Chemicals Program, CFIA