



*Our strength is innovation. Our commitment is to improving the quality of life.
Notre force, c'est l'innovation. Notre engagement, c'est d'améliorer la qualité de la vie.*

econiche[™] Backgrounder

About Bioniche Food Safety

The Bioniche Food Safety Division of Bioniche Life Sciences Inc. was established in 2001 to research, develop, manufacture, and market livestock vaccines to improve the safety of food and water supplies and the environment, thereby reducing health risks to humans.

The *E. coli* O157:H7 vaccine - *Econiche* - is the lead initiative of this division, behind which, a pipeline of other food safety products is being developed, in partnership with the Vaccine & Infectious Disease Organization (VIDO) at the University of Saskatchewan.

Origin of *Econiche*

Econiche has been developed by a strategic alliance formed in September, 2000 and composed of the University of British Columbia (UBC), the Alberta Research Council (ARC), the University of Saskatchewan's Vaccine & Infectious Disease Organization (VIDO), and Bioniche, which holds the rights for worldwide commercialization of the vaccine.

Dr. Brett Finlay at the University of British Columbia (UBC) made the original scientific discoveries that led to the development of the vaccine. He was doing basic research in the laboratory in 1995 when he made a fundamental discovery: That the *E. coli* O157:H7 bacteria secrete proteins that, once in contact with intestinal cell walls, serve as receptors that enable the bacteria to adhere and colonize the intestines.

Dr. Finlay realized that it might be possible to immunize against the attachment proteins of the bacteria. It initially occurred to him that this could be useful in childhood vaccines. He subsequently determined that a cattle vaccine might be the better opportunity to pursue. He approached the Vaccine and Infectious Diseases Organization (VIDO) at the University of Saskatchewan to assist in making secreted proteins to immunize cows.

Bioniche Life Sciences, through the Canadian Bacterial Diseases Network (CBDN), became the commercial partner on the recommendation of Dr. Dragan Rogan, Vice-President of Animal Health research at Bioniche, who recognized the potential of the vaccine and the need for it. The partnership of UBC, VIDO, the Alberta Research Council and Bioniche, led by Dr. Rogan and his team, developed the vaccine.

In terms of financing, Bioniche Life Sciences was granted a contract (repayable loan) with Technology Partnerships Canada (TPC) in 2001, for the development of this vaccine. TPC agreed to contribute \$7.6 million Cdn. to this project.

Additional repayable financing has been provided by the Ontario government, Agriculture Canada, and the Business Development Bank of Canada. The combined financings are being utilized to scale-up vaccine production at the Company's Belleville, Ontario facility.

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Research Results with *Econiche*

Over the last several years, important contributions in efficacy evaluation have been made by the University of Nebraska-Lincoln, led by Drs. Rod Moxley and David Smith. These studies have shown that the vaccine, under field conditions, performs very well and contributes to a highly significant reduction in shedding and colonization of *E. coli* O157:H7 in cattle. The process of establishing these benefits has been lengthy, expensive and detailed.

To begin, data simulations and modelling studies based on 5,000 penned animals were used to estimate the effect of vaccination on the summer pattern of *E. coli* O157:H7 shedding in feedlots. These data were used to predict that the Bioniche vaccine would reduce the summer shedding to approximately the same level of shedding as is seen in the winter, a level that is more readily controlled.

Findings from other trials also indicated that active shedding is the source of *E. coli* O157:H7 infection and spread in a feedlot, rather than infection from the environment. This is bolstered by data demonstrating that frequent pen cleaning (by scraping of manure from the concrete) did not reduce the *E. coli* O157:H7 infection rate in a feedlot.

Field studies and clinical trials have been conducted with the vaccine over the past five years involving more than 30,000 cattle. Studies have consistently shown a significant decrease in the number of cattle shedding these deadly bacteria in their manure. In a controlled experiment conducted at VIDO, vaccinated cattle were challenged with a very large dose of bacteria, and there was a reduction in the magnitude of shedding by 99.47%. In clinical trials conducted by the University of Nebraska-Lincoln in commercial feedlot settings (where vaccinates and non-vaccinates were mixed), there was a 75% lower prevalence of *E. coli* O157:H7 in cattle vaccinated with two doses of the vaccine. Another three-dose vaccination study was performed by the university, which showed that vaccinated cattle were 98.3% less likely to colonize the bacteria in their intestine.

In summary, the Bioniche *E. coli* O157:H7 vaccine has undergone an unprecedented level of testing for an animal vaccine. Consistently positive results are being seen in feedlot settings, where the *E. coli* O157:H7 bacteria are most prevalent, and where the Company will first market the vaccine upon licensing.

Current Status of *Econiche*

The vaccine has been granted a full license by the Canadian Food Inspection Agency (CFIA). In February, 2008, the Company received notice from the United States Department of Agriculture (USDA) that the vaccine is eligible for conditional license. The Company must complete a manufacturing step in the United States and provide a plan to satisfy final efficacy requirements, after which a conditional license will be issued.

FOR FURTHER INFORMATION, CONTACT:

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