

**Cattle Vaccine Update:
Epitopix Receives USDA Conditional License For America's First E. Coli O157 Vaccine For Cattle**

March. 10, 2009

Source: Epitopix news release

The United States Department of Agriculture (USDA) has granted a conditional license to Epitopix, LLC for America's first E. coli O157 vaccine for cattle. The vaccine is made with Epitopix' exclusive SRP Technology, an innovative, patented vaccine production process. The new vaccine is labeled for use in cattle to reduce the prevalence of the E. coli O157 carrier state and for reduction in the amount of E. coli O157 shed in feces to minimize E. coli exposure and infection of herd-mates.

"Our new E. coli O157 Bacterial Extract is the first O157 vaccine licensed for sale in the United States. It represents a significant breakthrough in the beef industry's on-going effort to reduce E. coli O157," according to Epitopix General Manager, Jim Sandstrom, speaking at the Beef Industry Food Safety Council (BIFSCO) meeting in San Diego, California.

Although the product license is conditional while additional potency and efficacy studies are completed, the USDA approval allows Epitopix to make the vaccine immediately available for use by the beef industry. E. coli O157 Bacterial Extract is the first immunological weapon available to the industry in the battle against this food safety concern.

The innovative SRP vaccine production process was developed by a team of Epitopix scientists led by Dr. Daryll Emery, Darren Straub and Doug Burkhardt. Their work together, with scientific assistance from two prominent beef industry experts, Dr. Dan Thomson of Kansas State University and Dr. Guy Loneragan of West Texas A&M University, was critical to receiving USDA approval.

Thomson and Loneragan helped design and carry out the clinical trials and large-feedlot efficacy studies needed to meet USDA requirements. "The collaborative studies we conducted with help from these two well-respected scientists from two great academic institutions, formed the basis for USDA's reasonable expectation of vaccine efficacy, a critical component for granting a conditional license," Sandstrom added.

E. coli O157 is a Gram-negative bacterium known to exist in the gastrointestinal tract of outwardly healthy, normal cattle. These bacteria do not cause disease in cattle, but when the cattle are harvested, E. coli O157 bacteria can sometimes find their way into ground beef. Proper cooking easily kills the bacteria, but in cases where beef may be inadequately cooked, serious human disease can occur, especially in children, the elderly or in individuals with a compromised immune system. Symptoms of the disease in humans range from mild stomach upset to severe diarrhea, or, in rare cases, Hemolytic Uremic Syndrome (HUS), which can be fatal.

For several years the beef production industry has waged a multi-front battle against E. coli risk factors. "Throughout this fight, the USDA and the National Cattlemen's Beef Association (NCBA) have been encouraging and providing assistance to a number of public and private E. coli pre-harvest and post-harvest intervention strategies," Sandstrom says. "It is exciting for Epitopix that we may now deliver the first immunological control tool to a very determined beef production

industry. We are confident that our E. coli O157 SRP vaccine will play an important role for beef producers and packers as they work together to implement E. coli O157 control efforts."

Epitopix' first major SRP-based vaccine for cattle, Salmonella Newport Bacterial Extract, received a USDA conditional license in 2004 and is marketed by Agri Laboratories, Ltd. of St. Joseph, Mo. The Salmonella SRP vaccine has been used in millions of U.S. dairy cattle, and is now in the final stages of qualification for a full USDA licensure.