

## UNITED STATES ANIMAL HEALTH ASSOCIATION - 2005

**RESOLUTION:** 21 APPROVED

**SOURCE:** COMMITTEE ON FOOD SAFETY

**SUBJECT MATTER:** DEVELOPMENT AND APPROVAL OF SAFE AND EFFECTIVE VACCINES TO REDUCE THE RISK OF *E. COLI* O157:H7

**DATES:** Hershey, Pennsylvania – November 3-9, 2005

### **BACKGROUND INFORMATION:**

It is well documented that the presence of *Escherichia coli* (*E. coli*) O157:H7 in improperly cooked ground beef or cross contamination of other food items is a significant public health threat. The United States Department of Agriculture (USDA) declared *E. coli* O157:H7 an adulterant in ground beef in 1994 and in 1996 developed the Hazard Analysis and Critical Control Points (HACCP) regulatory framework that establishes a science- and risk-based approach to reducing food safety risks. Since the implementation of HACCP and the development and adoption of in-plant interventions that improve the microbiological profiles of meat products, the Centers for Disease Control and Prevention (CDC) has documented very significant declines in the rates of food-borne illness in the United States.

However, despite the recognition that reducing food-borne illness requires interventions at each step from the farm to the table and after over 12 years since *E. coli* O157:H7 was declared an adulterant, no viable or effective preharvest interventions have been developed and approved to reduce the risk of *E. coli* O157:H7. One reason for this is the existence of uncertain regulatory approval procedures, processes and authorities. Recent research indicates there is a significant opportunity to develop safe and efficacious vaccines to reduce the risk of *E. coli* O157:H7 shedding in cattle. However, the regulatory process necessary for review and potential licensing of a safe and efficacious vaccine is uncertain and an impediment to reducing the risk of *E. coli* O157:H7 at the preharvest level and subsequently reducing food safety risks.

### **RESOLUTION:**

The United States Animal Health Association (USAHA) supports and encourages the United States Department of Agriculture (USDA), Animal and Plant Inspection Service (APHIS), Veterinary Services (VS), Center for Veterinary Biologics (CVB) to work closely with the Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) to allow the USDA-APHIS-VS-CVB to assume the review, approval and licensing process for vaccines used in animals that have a benefit in reducing food safety risks. The USDA-APHIS-VS-CVB has extensive expertise, experience, test facilities, inspection unit, and existing framework to regulate vaccines of this type. In addition, USDA has the authority to regulate vaccines for use in animals pursuant to the Virus Serum Toxin Act, in Title 9, Code of Federal Regulations (CFR), and an existing Memorandum of Understanding (MOU) with the FDA dated June 18, 1982, indicated the agreements to play this role have long been in place. USAHA urges USDA-APHIS-VS-CVB to work with FDA to quickly establish the clear regulatory path at the USDA for these important contributors to food safety.

### **RESPONSE:**

#### **ANIMAL AND PLANT HEALTH INSPECTION SERVICE, VETERINARY SERVICES (APHIS-VS)**

The Center for Veterinary Biologics (CVB) and the Food and Drug Administration (FDA) have worked closely to clarify the regulatory jurisdiction of vaccines such as *Escherichia coli* O157:H7 for

use in cattle. The outcome of those discussions were made public in the Center For Veterinary Biologics Notice No. 05-07, Biologics for Reduction of Colonization and/or Shedding in Animals. The notice informs industry of a change in APHIS policy regarding licensing requirements for veterinary biological products with a claim of reduced colonization and/or shedding of organisms that may not cause significant clinical disease in animals, but have the potential to adversely impact the management or care of the animal by causing the animal to be a disease carrier. The notice states:

*In response to requests from industry, the APHIS and the United States Department of Health and Human Services, Food and Drug Administration (FDA) have agreed that the jurisdiction for animal vaccines targeted at the reduction or elimination of a carrier state of organisms that can infect other animals (even if that infection is only rarely associated with significant clinical disease in animals), will lie with APHIS as long as certain criteria are met.*

*Those criteria include:*

- 1. Products must be indicated for administration to animals only, and must act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response.*
- 2. Label claims and advertising must contain only factual statements supported by data (e.g., as an aid in the reduction of colonization and/or shedding). No food safety or human health claims, either implicit or explicit, would be allowed by APHIS. Products with such claims would fall under the authority of the FDA and require their approval.*
- 3. The products will be required to show significant, substantively meaningful, and clinically relevant efficacy as defined by APHIS. For claims of reduction of colonization and/or shedding, products must demonstrate the ability to cause a substantial decrease in number of animals colonized and/or numbers of organisms shed by vaccinated animals.*

This jurisdictional clarification does not realign regulatory authority of vaccines that make overt human health claims away from FDA to CVB. However, it does offer a mechanism for licensure of vaccines that reduce shedding of pathogens and can therefore add value to food animal production by positively affecting the management of animals. It also still allows vaccine manufacturers wishing to market products with human food safety claims the ability to apply for and obtain FDA licensure.