UNITED STATES ANIMAL HEALTH ASSOCIATION - 2004

RESOLUTION NUMBER: **20** **APPROVED**

SOURCE: COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY
COMMITTEE ON FOOD SAFETY

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

DATES: OCTOBER 27, 2004

BACKGROUND INFORMATION:

There are various emerging biological products that immunize and treat animals to reduce infection, shedding, colonization and/or bioburden in the intended animal. For example it is well documented that 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. 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 that there is an 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) to work closely with the United States Department of Health and Human Services (USDHHS), Food and Drug Administration (FDA) to allow USDA, Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (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 has extensive expertise, experience, the 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 with the FDA dated June 18, 1982, which indicates that the agreements to play this role have long been in place. The USAHA urges the USDA to work with FDA to quickly establish the clear regulatory path at the USDA for these important contributors to food safety.

RESPONSE:

AGRICULTURAL RESEARCH SERVICE (ARS)

The Agricultural Research Service (ARS) will use agency expertise, experience, and testing and research facilities to work with APHIS, CVB and FDA to the extent possible to secure the necessary data to facilitate approval of biological products that immunize and treat animals to reduce infection, shedding, colonization and/or bioburden of food safety pathogens in food producing animals.

ARS has considerable expertise in the areas of basic and applied immunology and the use of antivirals used in conjunction with vaccination to reduce animal disease and mortality. ARS will continue to work with appropriate regulatory agencies and the drug industry to reduce pathogens in the food supply and protect this Nation's animal industries.

FOOD AND DRUG ADMINISTRATION (FDA)

FDA recognizes that the development of animal vaccines for certain disease may have significant human health benefits as well. As you know, FDA has a Memorandum of Understanding with USDA on cross-jurisdictional products. FDA is currently working with USDA on these vaccine issues. The agency appreciates USAHA's support of this work.

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

The Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), and the Department of Health and Human Services, Food and Drug Administration, 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. On March 4, 2005, APHIS announced this policy change and published guidelines (which includes required criteria) in Center for Veterinary Biologics Notice 05-07, which can be viewed at the following website:

http://www.aphis.usda.gov/vs/cvb/notices/2005/07.pdf