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The Committee met on October 4, 2011 at the Adam's Mark Hotel in Buffalo, New York, from 1:00 pm to 5:30 pm. There were 28 members and 38 guests present. Dr. Norman welcomed committee members and guests. She reviewed the committee purpose and guidelines for conducting the meeting.

FDA Update on the Food Safety Modernization Act Dr. Burt Pritchett, FDA, Center for Veterinary Medicine

Dr. Pritchett gave an overview of the Food Safety Modernization Act, or "FSMA", and the timeline for publishing rulemaking to implement the new legislation. FSMA was passed by Congress in December 2010 and signed by the President on January 4, 2011. It amended the Federal Food Drug and Cosmetic Act so it applies to FDA regulated food (both human food and animal feed), but does not apply to food regulated by USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

One of the main goals of FSMA is to build more prevention into the manufacturing, processing, packing, and holding of food, rather than reacting to problems after they occur. FSMA also provides new tools for inspecting for industry compliance with food safety regulations, and for responding to food borne illness outbreaks, and incidents where potentially hazardous products enter commerce. The new legislation also addresses the safety of imported food. FSMA relies heavily on partnerships with state, local, and other federal agencies for the success of the new food safety system.

The statutory deadline for publishing final regulations that will require human food and animal food facilities to implement hazard analysis and risk-based preventive controls is July 3, 2012. This means that a proposed regulation needs to be published this October or November to allow time for public comment on the proposed requirements.

USDA Swine Influenza Surveillance Dr. Sabrina L. Swenson, USDA National Veterinary Services Laboratories

Swine influenza primarily presents as a respiratory disease of swine manifested as elevated body temperature, coughing, sneezing, dyspnea, and/or nasal discharge. In many instances the disease is self-limiting with a high mortality rate and low morbidity rate. Secondary viral or bacterial infections may occur following infection with swine influenza virus (SIV).

Influenza viruses are RNA viruses and have segmented genomes. Prior to 1998, swine influenza in pigs was caused by H1N1 SIV which is referred to as classical SIV. In 1998 it was recognized that a new virus had entered and become stable in U.S. swine population. This virus was a H3N2 virus referred to as a triple reassortant virus, as the virus was composed of genes from human isolates, isolates from avian species, and isolates from swine. Over time the H3N2 and H1N1 viruses underwent reassortment (swapped genes) resulting in new viruses such as H1N2 and H3N1. Changes in the hemagglutinin (H or HA) over time has resulted in the recognition of 4 distinct H1 types (alpha, beta, gamma, delta) in swine. As a result there are now multiple influenza subtypes being maintained in the U.S. swine population.

In 2008, the Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture (USDA) began exploring opportunities to implement SIV surveillance in swine to develop a better understanding of what viruses were circulating in the U.S. swine population. This collaboration occurred as

a result of joint investigations between CDC and USDA into human infections with swine lineage influenza. In 2009, prior to implementation of the surveillance plan, pandemic H1N1 appeared in people and animals. As a result the basic plan developed by CDC and USDA was enhanced, and the surveillance testing was launched in May, 2009.

The surveillance effort was implemented through the National Animal Health Laboratory Network (NAHLN) that was already in place for testing for agriculturally important animal diseases. The NAHLN labs were provided with a PCR procedure for detection of the matrix gene of influenza. The matrix assay was already being used for detection of avian influenza in the labs, but was modified to also detect the pandemic matrix. Labs were also provided with an N1 PCR procedure specific for the N1 that was unique to the pandemic influenza. The testing algorithm involved screening for influenza using the matrix assay, followed by the N1 assay to determine if pandemic influenza was involved. Labs also conducted virus isolation and sequencing for the hemagglutinin, matrix, and neuraminidase genes. All viruses isolated are sent to the National Veterinary Services Laboratories for development of a swine influenza repository, and the genetic sequences of the three genes are deposited into GenBank, a publically available database.

Samples entering the surveillance system are on a voluntary basis and can enter through two streams, identified and anonymous. Under the identified stream, the producer and herd location are known by USDA. Under the anonymous stream, the producer is not known by USDA, and the herd location is only by state and not by specific address. Initial swine producer concerns and lack of participation led to implementation of the anonymous system in July, 2010. Since then, numbers of samples entering the SIV surveillance system has been increasing. As a result, available sequence data in GenBank for U.S. swine have increased, and viruses have been arriving at NVSL for the repository. Data are now becoming available on the types of viruses identified as well as states in which those viruses are being found. The availability of a national repository of viruses and national data have been extremely helpful during recent investigations of suspected human infections with swine lineage influenza and in identifying development of new viruses as genes move from one virus to another.

One Health: the APHIS VS Perspective and an Update on APHIS/VS Activities

Dr. John Clifford, USDA APHIS VS

Dr. Thomas Gomez, USDA APHIS VS

Within USDA-APHIS-Veterinary Services (VS) we've been talking for the past three years about the ever-changing landscape of animal agriculture and about the need for VS to adapt to better meet the needs of our partners in the States, Tribes, industries, and universities now and in the future. That has been the guiding principle of the organizational change effort we've been calling "VS2015" and is detailed in our document "Veterinary Services: A New Perspective". In response to the most pressing needs of today, VS has identified a specific group of priority issues to be addressed in 2011 and 2012. These priorities include One Health and further integrating One Health activities into our daily work.

While the health of animals remains our primary focus, we are also aware of how the health of animals (including domestic and wild animals), the health of people, and the viability of our ecosystems are inextricably linked. As part of its vision now and for the future, VS is committed to embracing One Health as part of the solution to prevent and control diseases at the human, animal, and environmental interface. That is why VS is contributing its expertise, infrastructure, and systems to partnerships that span counties, States, and countries to promote healthy animals, people and ecosystems.

To this end VS is implementing its "New Perspective" and "One Health Strategic Plan" which map out the future direction of VS. As part of implementing its "One Health Strategic Plan" VS is developing communications and training/education plans and an operational plan which will focus on two areas – determining VS' role and activities in zoonotic diseases and pre-harvest food safety.

In conclusion, Veterinary Services will continue to broaden the scope of its mission to collaborate with one health partners to optimize human, animal, and environmental health.

The Raw Milk Movement, a Minnesota Perspective

Dr. Joni Scheffel, Minnesota Department of Health

Despite outbreaks and the fact that raw milk is a risky food, there are claims by some consumer groups that perceived benefits outweigh any risks. Related to this, there is a movement in the US to relax regulations regarding sale of raw milk. During the 2010-2011 legislative season, raw milk bills were introduced in at least 10 states including Minnesota. Opposing these legislative efforts is made more difficult for health departments and regulators because of the misinformation regarding raw milk available to consumers on the internet and through other social media.

Outbreaks associated with raw milk occur frequently and receive media attention. However, only a minority of raw milk consumption-associated illnesses are part of recognized outbreaks. "Sporadic" cases of illness (those not associated with an outbreak) represent a much larger public health issue than outbreaks. In Minnesota, from 2001-2010, 518 of 13,222 persons with sporadic cases of enteric illnesses such as *Campylobacter* and *Salmonella*, reported drinking raw milk during the incubation period of their illnesses. During this same timeframe, five raw-milk associated outbreaks were identified, accounting for 23 cases. The number of laboratory-confirmed sporadic cases was 22 times the number of raw milk –associated outbreak cases. There is a significant burden of illness associated with raw milk consumption, disproportionately born by children, as 37% of sporadic cases in Minnesota are less than 10 years of age.

Q Fever

Dr. Lynn Creekmore, USDA APHIS VS

The recent, and historically large, outbreak of Q fever in the Netherlands has brought renewed attention to the presence of *Coxiella burnetii* in the US and the question of whether such a large outbreak could occur in this country. *Coxiella burnetii* is a widespread, obligate intracellular gram negative bacterium for which the main reservoirs of infection for humans are cattle, sheep and goats. People are most often infected through aerosol transmission of the organism around the time of livestock parturition. The majority of studies in the US have focused on dairy cattle (estimated prevalence 78.6%), while the national prevalence in sheep and goats is unknown. There are variable state requirements to report Q fever, and there are variable state responses to positive herds or flocks with some quarantining while others cite the disease is endemic and don't respond. The growing US goat population, increase in new goat producers, and expanding human populations into previously rural areas along with heightened interest in lambing/kidding/calving at state and county fairs all escalate the risks for human exposure. Enhanced and consistent reporting along with uniform response to acute livestock infections nationally and improved understanding of the prevalence and epidemiology in small ruminants will ameliorate the situation. However, there is also a need for producer education and viable control options (such as vaccination) for producers who want to prevent or reduce the risks for Q fever in their herds or flocks.

Update on the 2011 NASPHV Rabies Compendium

Dr. Don Hoenig, State Veterinarian and State Public Health Veterinarian, Maine

Dr. Hoenig reviewed changes in the current Compendium for Animal Rabies Control. The new document was released in May 2011. Changes include a new case definition, clarification in the role of CDC, and statements about live animal testing. Additional research topics for further study are added and the list of approved rabies vaccines is updated.

Evaluation of ONRAB[®] Oral Rabies Vaccine (Rabies Vaccine, Live Adenovirus Vector {AdRG1.3}) in feral dogs (*Canis lupus familiaris*)

Dr. Scott Bender, Navajo Nation Department of Agriculture

ONRAB[®], a human adenovirus rabies construct vaccine, has been used in extensive field trials in Canada for several years to determine the safety and efficacy of the vaccine in target species (striped skunk, raccoon, and red fox). These trials also determined that the most common non-target species that may ingest baits are dogs. In support of use of the vaccine in the United States, the Navajo Nation Veterinary Program, Navajo Nation Department of Agriculture, Navajo (First) Nation applied to the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Center for Veterinary Biologics for a research and evaluation permit to evaluate the safety of ONRAB[®] vaccine in feral dogs.

Twenty feral dogs, kept in isolation, were offered ONRAB[®] vaccine contained in "Ultralite" baits (Artemis Technologies Inc., Guelph, Ontario, Canada). General health status was monitored and sera collected at day 0 and at 2 week intervals for the duration of the study, with seroconversion against HAd5 and rabies used to determine vaccine uptake. Oral swabs collected at 2, 12, and 24 hours post-bait consumption, and rectal swabs at 48 and 72 hours post-bait consumption were assayed for AdRG1.3 by Real Time Polymerase Chain Reaction (PCR) to evaluate potential environmental virus shedding. Two human subjects (investigation veterinarian and one animal caretaker), two non-study, investigator-owned dogs and one unvaccinated control dog kept in intimate contact with four vaccinated dogs, were assessed pre- and post-study for HAd5 and rabies titers changes or seroconversion, to monitor for potential horizontal transmission. Canine Adenovirus type 2 titers were determined for potential interference with the AdRG1.3 vaccine. AdRG1.3 was titrated from one unused bait to assess any degradation due to shipping and storage of the vaccine during the study. Uptake of the ONRAB[®] vaccine by titer seroconversion or booster was observed in

a majority of the dogs, with no adverse health effects from vaccination noted during the course of the study. Pre-existing CAV2 titers had no apparent effect on the AdRG1.3 seroconversions. While shedding was detected by the swabs, no indication of a horizontal transmission to humans, non-study dogs or the dog in intimate contact was observed. Shipment did not cause any detectable degradation in the returned unused bait.

No adverse effects were observed by the vaccination of dogs using ONRAB[®] oral Rabies vaccine. In conclusion, the ONRAB[®] AdRG1.3 vaccine results in this study show its potential as a viable Oral Rabies vaccine for use in the vaccination of feral dogs.

Spatially Explicit Capture Recapture Analysis of a Raccoon Density Index

Dr. Kurt VerKauteren, USDA APHIS WS

Dr. VerKauteren reviewed methodologies for estimating raccoon populations. Accurate estimates are desirable to best determine bait drop density for oral rabies vaccination programs and for determining seroconversion rates after vaccination. A new model incorporates spatial data and yields higher density estimates compared to current methodologies.

Invitation and Highlights of the Rabies Symposium

Dr. Joanne Maki, Merial

Dr. Maki stressed the global importance of rabies. She provided a review of the Rabies Symposium being held on October 5, 2011 and encouraged attendance. She also reminded people of the One Health luncheon following the symposium and encouraged attendance.

Committee Business

The committee had one Recommendation: The committee recommends that a One Health based symposium be held again next year. The symposium would be similar to the Rabies Symposium held this year, but on a different topic. The committee believes this is an effective means to provide an opportunity for in-depth discussion on a topic and to encourage participation of the public health community.

The committee passed two resolutions, which were forwarded to the Committee on Nominations and Resolutions.