

REPORT OF THE COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY

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The Committee met on October 6, 2011 in Buffalo, New York, from 8:00 a.m. to 10:00 a.m. Joe Huff acted as Chairman in the absence of Bob Pitts and Jim Wolfram. Joe Huff welcomed everyone and reviewed the Committee's Mission Statement, followed by presentations.

APHIS, VS-Center for Veterinary Biologics Update

Presenter: Dr. Richard Hill, Director for the Center of Veterinary Biologics, Ames, Iowa

The Center of Veterinary Biologics provided an overview of key APHIS, Veterinary Services, and Center initiatives. VS' strategic roadmap "VS 2015 – A New Perspective" outlines the organizations goals for the future. The primary focus of VS2015 is to enhance the core strengths that have made VS a leader in animal health. The document lays out a refocused vision and mission and the goals that ensure our role as the Nation's animal health leader for the 21st Century. These goals include more flexible, transparent regulatory frameworks, innovative approaches to animal import and export, new tools for emergency management and expanding services related to One Health and wildlife. In the area of surveillance, VS will continue work on a comprehensive, integrated surveillance system which will include broad-ranging data for analysis, decision making, and generating timelines that address commodity-specific surveillance plans. The new approach for managing Bovine Tuberculosis Programs is continuing. Regulations and requirements are being developed as outlined in the Concept Paper published last year and the feedback from the State/Federal/Tribal Working Group that received input during multiple public meetings. The new facilities at the National Center for Animal Health (NCAH) were briefly discussed. There are still some infrastructure and demolition projects pending for FY 2012. CVB program activities for the first ¾ of fiscal year 2011 were reported. Although the number of licenses issued this year has decreased, most other metrics followed recent trends. Final numbers and metric reports from CVB Inspection and Compliance and CVB Policy, Evaluation and Licensing will be posted to the CVB website at the end of the fiscal year. The Operational Priorities for the Center fiscal year 2012 focused on business process improvements due to reduced staffing and steady or increasing workload. Included in this initiative are the activities around Single-Tier Label Claims and Electronic FOIA, finalizing last year's Laboratory Development Projects related to improving 9 CFR standard requirements, and implementing an electronic system for pharmacovigilance.

NADC, Prion Research Update

Presenter: Dr. Robert A. Kunkle, Veterinary Medical Officer in the Bovine Prion Research Section

Topic: Prion diseases of animals research perspectives from the Virus and Prion Diseases of Livestock Research Unit at the NADC.

Robert A. Kunkle, Eric M. Nicholson, Justin J. Greenlee, Jodi D. Smith, and Marcus E. Kehrl Jr.

The National Animal Disease Center is one of three USDA centers in the National Centers for Animal Health. As part of the USDA-Agricultural Research Service, NADC is a national resource where roughly half of the ARS animal health research program is conducted with a current Congressional appropriations of \$32 M/year. The NADC is made up of 4 research management units consisting of 13 separate research projects directly supported by 46 PhD-level scientists along with 6 additional currently vacant scientific positions. These scientists are supported by a highly skilled and trained technical and animal care support staff, as well as a facilities operation support staff.

In the Transmission, Differentiation, and Pathobiology of Transmissible Spongiform Encephalopathies project much of our research has direct bearing on national surveillance of prion diseases of livestock and wildlife. We have been leading research in assessing the cross-species transmissibility of TSEs, defining differential diagnostic characteristics of prion diseases in unnatural hosts and expanding and refining tools for ante- and postmortem diagnosis.

We discovered a novel prion allele in the 2006 BSE case that is a germline mutation and may represent a genetic form of BSE; research efforts are underway to verify this as a genetic cause of BSE. We recently demonstrated that the H-type BSE associated with the E211K polymorphism is transmissible with a faster incubation time than BSE-H transmitted in cattle of standard genotype and is associated with antemortem retinal thinning and functional deficits of the visual system.

Findings of electroretinogram examinations have established means for ante-mortem diagnosis of TSEs based on retinal accumulation of prions. We have published on methods to detect CNS tissue contamination on meat and carcasses and to diagnose scrapie-affected sheep post-mortem by fluorescence spectroscopy. Our publications of methods to substitute formalin-fixed-processed tissues for genotyping and western blot diagnosis of TSEs have expanded post-mortem diagnostic capabilities and created tools for retrospective analyses of TSEs.

Our studies on cross-species transmission of TSEs have delineated species-barriers and relative susceptibilities to the TSE agents, and diagnostic criteria to differentiate TSE strains. Findings from a series of studies reveal it is possible to differentiate BSE in cattle from cattle with experimental intracranial inoculation-transmitted scrapie, CWD or TME of cattle and established that cattle are not susceptible to scrapie or CWD via natural exposure. We have established that raccoons are not susceptible to CWD, fallow deer are relatively resistant to CWD, and white-tailed deer are susceptible to scrapie whereas sheep are relatively resistant to CWD. Preliminary studies also indicate swine are resistant to natural exposure to CWD and scrapie.

The intra-species TSE transmission studies at the NADC have expanded knowledge of the influence of host genetics and prion strain in the clinical course and post-mortem differentiating diagnostic characteristics of scrapie, CWD, and BSE in their natural hosts. Sheep inoculated with scrapie strain x124 develop scrapie rapidly, within four to seven months. Recent findings indicate the Q171K polymorphism in the prion gene of sheep prolongs the incubation period. Sheep with natural genetic resistance to classical scrapie develop the disease after intra-cerebral inoculation, but unlike susceptible sheep do not accumulate PrP^{Sc} in the lymphoreticular system. We have corroborated findings of transmission of CWD to white-tailed deer by intravenous inoculation of blood from clinical CWD deer.

Committee Business

Due to the lack of quorum, there were no resolutions or other committee business. The meeting adjourned at 10:00 a.m.